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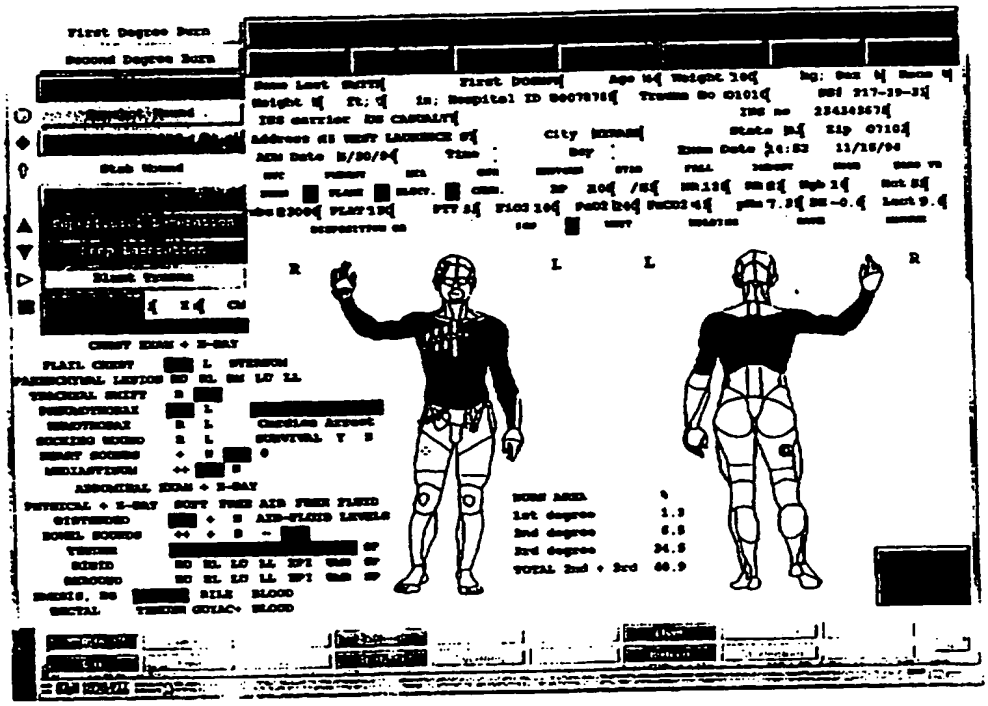
(57) Abstract

An interactive graphic computer methodology has been developed allowing a surgical resident or trauma surgeon to utilize a series of body images to record the location, type, complexity and physiology severity of trauma injuries via an interface device such as a mouse controller. The methodology incorporates, as a primary machine/human interface, a plurality of color graphic screens which share a common relational data base. Those graphic screen images include: (1) skin and superficial anatomy (for location of sites and types of injuries or burns), (2) skull, facial bones and CNS neurologic exam with automated calculation of GCS, (3) skeletal and joint anatomy (for orthopedic injuries), (4) spinal cord injury exam, (5) thoraco-abdominal viscera, (6) liver, pancreas and biliary tract, (7) retroperitoneal organs and structures, (8) vascular anatomy, (9) lung and tracheo bronchial tree. After data entry, injuries can be grouped for reporting and coding (i.e., fractures, organ injuries, lacerations, etc.). For specific types of injury, severity criteria are determined, therapeutic management guidelines estimated and state of the art therapeutic suggestions and cautions provided.



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# AN INTERACTIVE SYSTEM USING A GRAPHICAL INTERFACE FOR ASSISTING MEDICAL PROFESSIONALS IN THE DIAGNOSIS, TREATMENT AND MANAGEMENT OF SURGICAL AND TRAUMA PATIENTS

## FIELD OF THE INVENTION

This invention relates generally to systems for assisting medical professionals or para-professionals in the diagnosis, treatment and management of surgical and trauma patients, and the recordation and analysis of data related thereto, and more particularly to such a system embodying an interaction between the medical professional or para-professional and a stored electronic database via a computer driven graphical interface.

The publications and other materials hereof used to illuminate the background of the invention, and in particular cases, to provide additional details respecting its practice are hereby incorporated by reference, and for convenience are numerically referenced by the following text and respectively grouped in the appended bibliography.

## BACKGROUND OF THE INVENTION

In the treatment by medical professionals of diseased or injured patients, the time pressure of urgent patient care, the multiplicity of data and the ubiquitous deficiencies of record room function often conspire to produce inadequate or incomplete patient records, notably in regard to documentation of diagnostic findings and treatment protocols. This problem is particularly manifested in respect to care of the trauma patient, where such records should address both the primary and secondary injuries with regard to their anatomic, physiologic and metabolic consequences, as well as the critical resuscitative and therapeutic maneuvers appropriate to the trauma. In this setting, the multiplicity of injuries and the resultant demand for many different diagnostic technologies, combined with the immediate need for therapeutic modalities directed at the anatomic injury

and its physiologic consequences make effective record keeping a nightmare of inefficiencies. Even where it is mandatory, documentation is usually completed in urgent circumstances with often illegible results, and frequently results in inadequate paper records. When the chaos of record creation is compounded by record room inefficiencies and data transmittal errors, the ability to create and maintain an effective document for patient care, quality assurance and care reimbursement is impaired to a degree that effective management of the patient's disease or injury could be impacted, particularly where consultation with other medical and/or surgical professionals becomes necessary or desirable.

While attempts have been made in the past to apply computer techniques as a "living textbook" to the care of critically injured trauma patients, such efforts were limited by the inadequacies and costs of the large central computer system required to be dedicated to this use (11). However, the advent of networked computer technology and the improvements in the "intelligence" and processing power of the comparatively inexpensive distributed computers comprising such a network (i.e., the computer workstation), provides an opportunity to address this problem through an interactive, computer-driven process. As will be readily appreciated, the physician, the medical record establishment, a treating institution's financial interests and, most of all, the patient, can be benefitted by rapidly bringing effective documentation of the patient's condition and physiologic response to the responsible physician, without compromising the other necessary functions demanded by an ever more complex and bureaucratic health care system.

To address this problem, we have developed a simple, user friendly, automated system for use by a medical professional or para-professional for entry of physical examination and admission x-ray findings and admission physiologic data which will, in turn, produce a graphic and textual record of diagnosis for care needs, quality assurance and third party reimbursement requirements. That system is hereafter disclosed.

## SUMMARY OF THE INVENTION

A computer based interactive graphic methodology, and a system for carrying out that methodology, permit delineation and recording of physiologic, demographic and other relevant data for a diseased or injured patient. An interface with physiological monitoring systems and with radiological image data bases is supported by the invention, as is a graphical presentation of patterns of multivariable physiological data which describe, classify and quantify the adequacy of a patient's host defense response to injury (12).

The system of the invention is particularly applicable to trauma patients where injuries may be delineated and recorded with regard to their cause, severity and location both on the body surface and within the organs. The system can also record the consequences of blunt and penetrating traumas on the various organs and functions of the body.

The system further converts information about mechanisms of trauma and the patient diagnostic examination graphics, as entered by the physician using the graphical interface of the invention, into definitive textual statements, AIS 90 and diagnostic codings (ICD.9), and also permits the designations of therapeutic resuscitation and operative procedures, with their CPT codes. These data then can be used to fulfill medical record keeping, quality assurance and improvement, and third party carrier reimbursement requirements. Also, the delineation of details of admission physical exam abnormalities permits the identification of specific resuscitative and emergency surgical maneuvers that may be required.

With the system of the invention, admission physiologic and biochemical data are recorded and stored, thereby providing a time sequential clinical record in which updates of changes in the patient's condition and more in-depth system physical examinations by consulting specialists can be noted. In this way, an automated record is constructed which has both simple anatomically relevant explanatory

graphics as well as alpha-numeric and textual presentation capabilities. This also provides for a review of a patient's course either by examination of serial anatomic and physiologically based graphic representations of the patient's abnormalities or by generation of a textual record.

As an additional manifestation of the invention, the system allows the formatting of therapeutic advisories (Rx) which can be used to convey state-of-the art protocols and caveats relative to the specific conditions manifested by the patient. These advisories also provide rapid error free computation of drug dosage and protocols of administration for generally accepted urgent therapeutic agents (e.g., initial fluid replacement therapy for burn victims or body weight dependent initial steroid doses in patients with spinal cord injury).

The data created by the entry of graphic and category information produced by cursor or alphameric input can be transferred to a conventional data base supported by the standard statistical analysis program (ISAS SPSS, or SPLUS). These statistical programs can be assessed from the COZY interface at the bottom of each screen display.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a depiction of the graphical image for an initial examination screen according to the invention. That screen is specifically directed to body surface image and additionally includes identification demographics, E code, and third party carrier information.

FIG. 2 shows a screen image for localization of injuries to skull and facial bones and Glasgow Coma Scale (GCS) parameters to compute level of physiologic brain dysfunction (GCS score).

FIG. 3 shows a screen image for localization of motor, sensory and proprioception abnormalities and their completeness produced by blunt or penetrating injuries of the spinal cord.

FIG. 4 shows a progression of the injury shown in FIG. 3.

FIG. 5 shows a screen image for localization of skeletal fracture injuries and for sprains, ligament disruptions and dislocations of joints.

FIG. 6 shows a screen image for localization of injuries to thoracic and abdominal cavity viscera with delineation of injury severity.

FIG. 7 shows a screen image of the retroperitoneal organs and their major vascular supply and drainage.

FIG. 8 shows a screen image of anatomy of hepatic vascular segments, major portal and hepatic venous anatomy, extra hepatic biliary and pancreatic ductal anatomy.

FIG. 9 shows a screen image of anatomic scheme of the major arterial system, including the intracranial vessels, with each major segment or division designated.

FIG. 10 shows exemplary therapeutic procedures for trauma resuscitation with their CPT codes.

FIG. 11 shows a screen diagram of a motor vehicle passenger compartment, for localization of points of contact or contact intrusion which acted as causative agents for injuries previously designated by interaction with anatomic screen diagrams.

FIG. 12 (A, B & C) show exemplary therapeutic advisories for burn trauma patients.

FIG. 13 (A & B) show the screen images for patient reporting, following examination. FIG. 13A depicts the screen before entries are made, while FIG. 13B depicts the screen after such entries.

FIG. 14 (A, B, C & D) comprise a printout of an operative notes accessed via the patient report screen of FIG. 13, derived from information concatanted by the program from the anatomic injury location data, the severity code designation (which produces the ICD.9 coding) and the therapeutic procedure windows (which allows the relationship of the ICD.9 code for each specific injury to be linked to a CPT therapeutic code). This output also delineates the AIS (Abbreviated Injury Score) for each injury, the nature of the surgical procedure, the type of incision, and the occurrence of specialized aspects of the surgical operation (e.g., insertion of chest tube, blood transfusion, use of drains, etc.) and the physiologic and therapeutic characteristics of the patient at the time of completion of the operative procedure (e.g., intubation, occurrence of shock, and physiologic variable data). In addition, an alphameric text entry capability is available so that details of the procedure and unexpected complications or impressions can be delineated by the operation surgeon.

## DETAILED DESCRIPTION OF THE INVENTION

A computer based, interactive graphic methodology is disclosed herein for assisting a medical professional or para-professional in the management of abnormal physiological conditions, particularly with respect to the establishment and maintenance of record data regarding patient physiologic and demographic data and the establishment of relational linkage between such data and diagnostic and treatment protocols relevant to conditions defined by such data. As an illustrative utilization of the system and method of the invention, the discussion

herein will be focused on the application of that methodology to trauma cases, which will constitute a preferred embodiment of the invention. It will be readily apparent,however, to those skilled in the medical and surgical arts that the invention will be of great value in diagnosis, treatment and management for medicine and surgery patients, and the recordation of data related thereto.

In respect to the preferred embodiment, the interactive graphic methodology of the invention will permit an examining surgeon, surgical resident, physician's assistant or specialty surgical consultants to delineate and record traumatic injuries with regard to their cause -- keyed to a classification standard such as ICD.9 E codes (13), location on the body surface and internal body organs and structures, and with regard to their severity grade -- using a system compatible with the causation coding. The system also facilitates the recording of admission physiologic and biochemical data. The interactive graphic modules of the invention also permit the recording of a full neurological examination and the delineation of the location, nature and complexity of skeletal system fractures which are the result of a traumatic insult.

As a further manifestation of the information management capability of this system, program modules have been created which provide relevant therapeutic protocols and suggestions for prevention and management of acute problems which may arise in post trauma victims. These medical information (Rx) modules provide clinical therapeutic guidelines related to specific injuries and can be updated on a current concept basis. Such therapeutic guidelines allow the use of trauma protocols to guide rotating surgical residents, physician assistants, paramedically trained EMTs (or a surgeon or emergency physician with limited experience in handling the trauma condition in question), to immediately initiate therapy before experienced trauma/surgical/medical consultation and management is available. They provide systematic guidance for urgent therapy which can then be modified as the condition progresses, using the quantitative information

provided by the repeated interactive graphic delineation of patient injuries and their resulting progressing physiologic abnormalities.

Additionally, the system allows for the recording of acute surgical resuscitative therapies and initial and subsequent operative procedures with their CPT codes (14), and provides for a complete record of all injuries and admitting diagnosis with their ICD.9 codes.

Our discussion of the invention herein is generally divided among five major aspects of the invention. We begin with a discussion of the software architecture underlying the processes of the invention. Next we consider aspects of the system of diagnostic examination graphics including representative examples. The third discussion element is focused on the input-output for the recording of resuscitative therapies and surgical procedures (Sx). In the fourth element, we consider the functions of diagnostic and therapeutic record keeping. And in the final element, we describe the organization of the therapeutic advisory (Rx) systems, including a demonstration of a specific module.

A. SOFTWARE ARCHITECTURE

The medical graphics user interface application is based on the utilization of a library of real time transaction processing objects. In a preferred embodiment, these objects are written utilizing the American National Standard for Information Systems - Programming language C, ANS X3.159-1989, as well as The National Institute of Standards and Technology (formerly the National Bureau of Standards) Portable Operating System Interface for Computer Environments (POSIX) in order to comport with the Federal Information Processing Standard. All graphics are performed with X11 from the X consortium and the Open Software Foundation's Motif tool kit, operating with Release 5.

The use of these standards has produced highly portable client/server objects. These objects fall into configurable classes which are reused across the suite of programs. The major classes of objects include:

1. The drawing class produces a vector map of an anatomically correct drawing. The user can, by using an interface device such as a "mouse", point and click on an anatomical feature to indicate a point of injury. The injury will be displayed as an injury symbol, where each injury has a unique symbol code, or as a generalized area of injury designated by a change in the background color of the anatomical feature. The drawing class has a full feature editor, permitting the user to remove erroneous entries. This class is fully integrated with the database class which permits the user to analyze historical entries, do time-line analysis and to enter new injury information as an amendment to a prior examination. For numerous applications a list of anatomical names are displayed. When the user points at an anatomical feature, the name of the feature is highlighted.

2. The command class allows the user to select the current active injury code -- both ICD.9 and AIS 90 (8) coding are supported in the preferred embodiment. These codes may be associated with shaded 3-dimensional push buttons depicted on the screen which are selected with the mouse. The active injury code will be prominently displayed as is the legend of injury codes.

3. The advisory class provides the user with any useful medical information that may be available for the particular trauma condition. This function will automatically compute fluid therapy and dosages of medications based on height, weight and body surface area. This function also analyzes the examination to determine if therapeutic advisories are required for any special conditions (e.g., circumferential or facial burns or spinal cord injuries).

4. The database class permits the user to store, amend and retrieve patient information on an advanced network server. This server system, properly configured to one or more internal and/or external computer networks -- e.g., the

Internet, makes all patient information available throughout the treating institution, or world wide in the case of a system of such institutions. In using such a networked database, the user may list all patients in the database or selectively search for a patient name or ID number. The user will receive a list of patient examination dates and times which can be called up. The user may then file a completely new examination, or may file modifications to specific aspects of an old examination by editing, in or out, the change in the patient's condition. This creates a time sequential record of patient condition changes. This class will also permit the deletion or modification of an incorrectly entered old exam, but is password protected to protect against unauthorized changes.

5. The terminal I/O class is a non-interrogatory data entry system that permits the user to enter textual information about the patient including identification, insurance, admissions and physiologic data. It may be embodied as a form on the screen, where the user points to the blank to be filled in and enters the appropriate text from a keyboard.

6. The choice class produces a check list of conditions that may be found during an examination where the using physician points to and clicks on the appropriate box. Illustrative examples for this class are:

a. Chest exam + x-ray
b. Abdominal exam + x-ray
c. Glasgow Coma Scale Scoring
d. Central Nervous System and spinal cord neurologic function tests
e. indicators of sinus fractures and CNS fluid leaks, classifications of types facial fractures by LeFort class
f. Central Nervous System Brain hematomas
g. Joint sprains, ligament disruptions, and dislocations

h. Motor vehicle crash injury contact points
i. Severity of injury grades (I-VI)
j. Operative procedures with their CPT codes
k. Interfaces with physiological monitoring systems
l. Interfaces with radiological image data systems
m. Interfacing with Standard Statistical Data Base (EG SAS, SPSS, SPLUS)

As will be understood, numerous other classes of injuries or conditions may be defined.

The use of common objects across a repertoire of applications produces a systematic "look and feel", where all applications behave in a predictable manner, producing no surprises for the attending physician. Testing by the inventors has demonstrated that training times for use of the invention are trivial and that trainees readily infer the conduct of all applications having received training on a single module. The applications have been written as an abstraction layer over the Unix operating system with the Common Operating System Environment Workspace Manager in a manner that prohibits any direct interaction between the user and the operating system, negating any need for the user to learn Unix. The database of injuries is suitable for a broad variety of relational analysis, leaving medical staff in the enviable position of performing statistical analysis, patient billing, quality assurance, analysis of correlation between care and outcome as well as historical analysis of comparable patients from almost a purely graphic input.

## B. DIAGNOSTIC EXAMINATION SYSTEM

This Diagnostic Examination system is comprised essentially of a group of interrelated programs which enable and guide the recording of the physical examination and radiologic diagnosis of injured or burned trauma patients. It is

established to be utilized by paramedical or medical trained personnel who might have a relatively limited experience in the evaluation of the seriously injured patient. Therefore, it is based on the utilization of a consistent diagnostic graphic format based on a series of body images which can be addressed by the examiner in a systematic fashion. These allow the recording of abnormalities noted on direct physical examination, or on the basis of information that might be obtained by specialized diagnostic equipment providing radiologic or ultrasound imaging. The format also permits the introduction of biochemical and physiologic information that might be obtained from standard biochemical analytic devices or physiologic sensors. These data can be entered either electronically as digitized data obtained from a laboratory medicine analysis system -- using a networked connection to such a system, directly from a patient physiologic monitoring system via a hard-wired connection, such as an RS-232 interface, or by manual keyboard entry of appropriate numbers which quantify the parameters of physiologic function, such as blood pressure or heart rate. The system additionally permits time indexed serial recordings of all systems, so that the admission physical examination, physiologic data and laboratory information can then serve as baselines for the interpretation of later changes seen in subsequent examinations.

1. General Considerations And Organization

The initial diagnostic format, body surface image **(Skin/Body)**, is shown in FIG. 1. This image contains identification demographics, ICD.9 E code, and third party carrier information. As will be seen, this screen is also characterized by a number of graphically depicted "hot buttons" for localization of causative agents, physiologic data entry correlations to physical examination (PE) abnormalities and indicator buttons for findings that may be syntheses of PE and radiologic examinations, as well as a listing of **Workspace Names** at the bottom of image which allow selection of other anatomic images relevant to the abnormalities noted on PE, or after surgical exploration, CT, or angiographic studies. It will also be seen that the graphical image includes other "hot buttons" for therapeutic advisories **[Rx]** and Surgical and Resuscitative procedures **[Sx]**, which will be

described hereafter. These "hot buttons" and **Workspace Names** can be accessed by the use of an interface device such as a mouse controller or trac ball driven cursor.

This first image demonstrates an anatomic diagram of the front and back of the body surface delineated into identifiable regions for localization of injuries or other abnormalities. It is important to note that all of the various diagnostic formats can be called to the screen by placing the mouse driven pointer on one of the specific **Workspace Names** at the bottom of the screen. These allow for the selection of images relevant to injuries to the body surface area (**Skin/Body**), head, face and brain (**Skull/CNS**), neurologic injuries which involve the spinal cord (**Spinal Cord**), or skeletal injuries (**Skeleton**). Images of the thoraco-abdominal viscera (**Viscera**), of the retroperitoneal organs (**Retroperit**) and of the peripheral arterial circulatory system (**Vasc**) can also be selected to record injuries. More detailed images for anatomic localization of injuries to the liver lobes (and their segments), and to the extrahepatic biliary and pancreatic ducts are available (**Liver**). Another image screen (**Lung**), permits anatomic localizations of injuries and injury related pathologic consequences (atelectasis, pneumonitis, ARDS, Empyema) involving the lung lobes (and their segments) and the tracheobronchial tree. It will be readily apparent to those skilled in the art that additional body images and/or other workspace images may also be made available for access via **Workspace Names** from an initial screen.

In all cases the examiner will begin the recording of the diagnostic session with the body surface image (**Skin/Body**) associated clinical observations and physiologic data obtained on first examination after the trauma (FIG. 1). This body surface image is used to enter the findings of the initial physical examination and is of considerable importance in localizing the causative agents of all the traumatic injuries considered.

As shown in FIG. 1, the MOTIF WINDOW format for the delineation of the nature and location of traumatic injuries is designed to produce a computer based clinical record file which can replace other types of paper records. More important, all of these images can be directly communicated by a computer located on a network maintained by the treating institution to a similar computer in the institution's Record Room to establish a permanent record. Such image data can also be sent to another remote location, so that consultation with a more experienced Trauma Surgeon or consultant can be requested with sufficient details to allow the general nature and urgency of the request to be conveyed before the actual patient contact is established. That consultation examination can also be recorded.

The anatomic locations of the injuries and their severities are delineated by a vector location system. Accordingly, it is only the vector points which need to be transmitted to a consulting computer, as the resident program of the invention itself recreates the image. This allows for a very economical use of the system and reduces the amount of information which needs to be transmitted by network, thus preserving network communications for other aspects of institutional management and monitoring.

At the top of the initial graphic display [FIG. 1] is space for the patient's demographic information, which may be entered via the keyboard, or could be initiated by a magnetic card reader or other appropriate input device. These data include the patient's name, age, body weight, sex, and ethnic origin as well as an identifying unit number, social security number, a trauma or special study number, as well as patient address and any insurance information as required. This information can be modified appropriately to fit any specific record keeping system and could be automatically entered from an insurance plan or federal magnetic card for those patients whose identity is known at the time of admission. The date of examination is automatically entered based on the time of the initial entry of patient examination information. Subject to validation as an authorized

user, the examination time can be changed by the individual conducting the initial examination to reflect some earlier time period than the actual computer entry, where there has been a significant delay between the physical examination and the time of data entry. The sequencing of examinations with regard to time permits serial physical evaluations, using the image of each body system, to be made with their exact times recorded.

In conformity with the classification of injuries by the ICD.9 **E Code** utilized by the American College of Surgeons Committee on Trauma, the National Highway Traffic Safety Administration and the Fatal Accident Reporting System (FARS) and other data banks, the specific cause of injury, or the factors initiating the traumatic episode can be delineated by clicking the mouse pointer over the relevant trauma **E Code** designator at the top of the diagram. With this facility, a wide variety of trauma conditions can be identified and the **E-Code** designation will operate, as well, to influence the **Rx** Advisory program's selection of the proper cautions and therapeutic suggestions. For instance, in the case of burns it is possible to indicate whether the burn injury has been produced by flame, chemical, or electrical insult, or any combination of these. Although not part of the standard **E Code** designators, a new **E Code** delineator for barotrauma (**BARO TR**) has also been created. This module would provide guidance in respect to hyperbaric therapy for divers sustaining severe "bends" or for an astronaut who might sustain severe barotrauma due to Extra Vehicular Activity (EVA) decompression in space.

The physiological and relevant biochemical information obtained when an injured patient is placed on the physiologic monitoring system permit the hemodynamic, respiratory and metabolic consequences of the injury to be related to the physical injury examinations. In this way, changes in patient status can be assessed and the rate of alteration in physical injury severity can be coordinated with physiologic studies obtained by invasive or non-invasive sensor systems. These data allow categorization of the nature of the trauma and stratification of the trauma episode with regard to its severity. The acquisition and recording of these data are critical

to trauma severity staging, since most of the various scaling systems for injury severity utilize one or more of such physiologic and biochemical parameters, as well as the specific anatomic information regarding the injury and its severity.

In the utilization of the system of the invention, four diagnostic images and their associated physical and radiologic examinations fields will ordinarily be mandatory to a complete assessment: **Skin and Body Surface** (FIG. 1), **Skull and Central Nervous System** (FIG. 2), **Spinal Cord** (FIG. 3) and **Skeleton** (FIG. 4). The delineation of pulse abnormalities in the peripheral vascular exam (**Vasc**) is conditional and the remaining anatomic images (FIGs. 6-9) concern diagnostic findings generally observed at surgery, or discovered as a result of computed tomographic (CT) or angiographic exams. These are detailed below. In all cases, the presence of an examination with **no abnormal findings** can be indicated.

2. Skin And Body Surface Localization Of Injuries, Including Burns

The physical examination data indicated in each of the various body images presented in this system are entered by the use of the mouse pointer (or other cursor manipulator) and qualified by user interaction with the various soft keys or "hot buttons" provided on the graphic surface. On the left side of the image shown in FIG. 1 are a variety of these "hot buttons", which will be depicted in different colors. These permit the examiner to qualify the nature and the degree of injury with respect to the region of the body surface specifically designated using the mouse. In an alternative embodiment, a touch sensitive screen with a pointer can be implemented to function in exactly the same way. The system is designed to allow the "hot button" description to specify the injury to an area using the focal injury pointer (cursor) to locate the site of injury. For example in FIG. 1, the location and degree of a body surface burn (first, second, or third degree) are indicated by placing the cursor over the specific body area after first activating the "hot button" for that degree of burn ($1^0$,$2^0$, or $3^0$). Moreover, each designated region of the body is named with regards to its anatomic location so that a precise textual designation can also be developed for a written report. In

the specific case of burns, as the areas burned are indicated and their severity quantified, the program automatically sums the second and third degree burn areas, both individually by degree and collectively, so as to automatically compute a total percent of body surface burn. This, as noted later in the discussion related to Therapeutic Advisory (Rx), allows for the computation of an initial fluid replacement therapy for the burn patient.

Also as shown in FIG. 1, the examiner can localize the point of contact injuries, such as contusions, or penetrating injuries caused by gunshot, shotgun or stab wounds and can plot the course of superficial or deep lacerations or blunt traumatic contusions across the body surface. These local points of blunt or penetrating trauma can be designated by using the focal cursor after activating the "hot button" for gunshot wound, stab wound, blunt trauma, deep laceration, etc. This will cause a specific symbol to be placed over the point of entry or serial symbols along the course of a laceration or contusion. In a similar fashion exit wounds (gunshot, etc.) can be indicated by the specific injury symbol, modified by a double image (which may be created by using a different mouse button) over the point of exit of the penetration. This allows a precise designation of the body surface injury and/or its trans-corporeal course to be related to deeper injuries of body organs or skeletal structures, as shown in subsequent diagrams. Also as shown in FIG. 1, surface blunt contusions, can be designated and their localization on the body surface can be shown by activating the **blunt contusions** "hot button". More than one injury can be delineated for a given body surface region. This is also shown in FIG. 1 where both a blunt contusion and burn have occurred in the same area, as with an explosion injury followed by fire. If the surface injury (in this example a stab wound) has produced a deeper mass that can palpated in a specific body location it can also be designated by activating the specific mass "hot button" and the mass size and physical characteristics such as **expansion** or **pulseatility** can also be indicated.

3. Chest And Abdominal, Physical And Radiologic Examination

The importance of the specific "diagnostic indicators" of FIG. 1 is not only that they serve to record data, but also that they alert the examining individual to critical examination questions that need to be answered by all means available (observation, physical exam, x-ray diagnosis, etc.). For instance, the examiner is requested to provide information about chest wall stability, or the presence of a sucking chest wound, a shift of the trachea, the presence of a physical diagnostically or radiologically demonstrable pneumo or hemothorax and the location of lung parenchymal lesions. The characteristics of the heart sounds and the presence of any radiologic mediastinal widening are requested during the cardiovascular examination.

The abdominal physical examination is completed by recording the finding of specific signs and symptoms including information about the bowel sounds, the level of distension and the location of tenderness, rigidity or rebound. Radiologic or ultrasound identified presence of bowel air/fluid levels, or free intra abdominal air or fluid can be indicated. The presence and characteristics of any emesis can be designated and the results of a rectal examination including the presence of tenderness, or of overt or occult blood can be indicated. These specific pieces of information are critical to a complete physical examination in interpreting the severity of various types of injuries and if present, they must be delineated by the individual who has done the examination.

Finally, the clinical interpretation of the patient's physiological severity (i.e., shock, cardiac arrest) and its consequences (survival vs. death) as well as the patient's disposition following a resuscitation are specified. These clinically relevant data are then related to the physical examination characteristics with regard to the nature and location of injury in the program and used to call forth the appropriate therapeutic or diagnostic advisories or warnings. These therapeutic advisories can be activated by placing the mouse pointer over the Rx advice block and activating it to provide the information related to the findings recorded. An

example of such an **(Rx)** advisory will be shown for burn injury in the Therapeutic Advisory section hereafter. The immediate surgical and critical care resuscitation therapies utilized and their CPT codes for third party billing and Quality Assurance programs can also be indicated using a **pop-up** window activated by the **Surgical** and **Critical Care** block (Sx care).

4. Skull, Facial Bones And Central Nervous System Brain Injuries

The second image screen, as shown in FIG. 2, allows for the localization and recording of physical and physiological information related to injuries of the head, face and brain (**Skull/CNS**). In this image right and left sided skull diagrams are presented so that face and skull fractures can be designated, together with a set of questions regarding the level of over all Central Nervous System (CNS) neurologic function. These observations represent the information required to develop and compute the Glasgow Coma Scale (GCS) Score. As the examining individual records these data, the Glasgow Coma Scale Score is automatically computed. Information such as whether an emergency intubation (T) has been carried out for airway control can also be entered to modify the Glasgow Coma Scale Score computation (e.g., GCS 7T). In addition other information relevant to the neurologic examination regarding pupillary sizes and levels of reactivity, the gag reflex, dollseyes, and the cold caloric response can also be indicated. Impairments of neurologic function secondary to drugs or alcohol can also be designated. These simple physical neurologic examination responses have been shown to have major prognostic significance for outcome in brain injured patients (1) and also to be important with regard to quantifying the interaction of hypovolemic acidosis induced by oxygen debt (base deficit) in modifying the GCS determined severity of brain injury and the nature and urgency of the necessary initial therapeutic response. (2-3)

In addition by using the "hot buttons" and injury localization with the mouse pointer, it is possible to indicate the nature, location and severity of the injuries to various bones of the face or skull and the teeth. The details of these injuries will

of course be dependent on the accuracy of physical examination and the availability of diagnostic imaging capabilities, but these findings can be updated in sequential exams with their own time stamp, as the more detailed radiologic and computed tomographic (CT) examinations are completed. In the anatomic field of FIG. 2, as in the rest of the diagnostic figures, as the examiner places the mouse driven cursor over the location (right or left) of the anatomic bone fractured, the bone name lights up with the same color as the Fracture Severity code.

Of particular importance here is that the system allows all information to be integrated and presented for diagnostic decision making. Not only can the type and severity of fractures to the bones of the skull or face be indicated, (simple, comminuted, or compound and their combinations), but also for brain injury it allows the neurologic examination to be linked with information that can be obtained from diagnostic imaging (CT or MRI). Indicators for the presence and location of intracerebral bleeding or epidural or subdural hematomas allows these complications to be recorded, as well as any resultant shift of midline structures. The graphic integration of all of these data provides information of great diagnostic significance in determining the level of therapeutic response that may need to be initiated in a head injured patient.

5. Injuries To The Spinal Cord Resulting In Spinal Cord Functional Abnormalities

The second neurologic examination image **(Spinal Cord)**, as depicted in FIG. 3, is related to the evaluation of individuals with suspected spinal cord injuries. The examining physician and/or the neurosurgical consultant can indicate the nature of the initiating injury, and its location if that is known, such as one that might be associated with an external wound produced by a sharp object or missile, or due to blunt trauma causing a spinal column fracture. Placing the mouse cursor on the body image localizes the specific level and the side of the body at which a neurologic disfunction occurs. The presence of complete or partial motor, sensory and proprioceptive function is designated by touching the "hot button" and

localizing the cursor at the spinal cord level on the body image. Also whether the lesion is associated with similar abnormalities in neural cord segments distal to the site of the initial abnormality can be indicated. Specific "diagnostic indicators" are requested to delineate the quality of muscle tone and cutaneous sensation, and a **pop-up window** arises to allow the examiner to designate the quantitative status of motor function for muscles enervated by $C_5$ - $C_8$ and $L_1$ - $S_1$. Using these data, right and left side sensory and motor scores consistent with those designated by the National Spinal Cord Injury Centers Program are computed for the use of rehabilitation services.

Through the system of indicators and colors noted on the diagram, this information can be recorded for visual presentation so that it can be compared with later examinations that might be made on the same individual over the post injury time period during which therapeutic modalities are being administered. In this way the presence of an incomplete lesion can be identified, or a resolving, or worsening lesion clearly delineated, so that a certainty of diagnostic evaluation can be obtained, clearly noted and the observation time recorded. Since only motor and sensory function (intact, partial, complete) are shown in the neurologic figure, proprioceptor function is shown in the chart table indicating side and level. For purposes of demonstration an image is presented (FIG. 3) in which there is partial motor (red) and complete sensory (green) and proprioception (light blue) loss on the left side of the body, compared with partial sensory (brown) and complete motor (blue) and partial proprioception (yellow) loss on the right side. Progression to complete motor (blue), sensory (green) and proprioception (light blue) loss is shown in FIG. 4. Failure to do a complete neurologic exam because of patient coma, pharmacologic paralysis or urgent surgery can also be indicated. Also, the level of training of the examiner is requested (i.e., PA, Resident, Trauma Surgeon, Neurosurgeon).

In cases where the spinal cord injuries are associated with spine trauma, the information presented in the skeletal image of FIG. 5 can be directly correlated

with that presented in the neurologic examination image (FIG. 3). Since any image can be repeated as serial examinations are made and the times of the repeated examinations are automatically recorded, a worsening condition or a favorable response to therapy can be precisely documented. This information could be shared with a remote consultant by a direct network connection or telephone modem so that definitive decision making can be made relevant to the need for patient transfer from a non trauma center to a Level I Trauma Center with neurosurgical capabilities.

6. Skeletal Injuries

The presence, location and details of fractures to other bones of the skeletal system can also be indicated **(Skeleton)**, as shown FIG. 5. In this figure using the "hot buttons" and the mouse cursor, the specific location site of fractures, joint sprains, ligament disruptions and dislocations of various bones of the skeletal system including the vertebrae of the cervical, thoracic and lumbar spine, as well as the ribs can be localized (illustratively indicated by yellow triangle) and the type and complexity of the fracture indicated (hot button color). As with the bones of the skull, placing the mouse cursor over a given bone region causes the name to light up in the color of the injury type and severity "hot button" designated. When the mouse button is activated the color remains in the designated location and side. In addition, other information associated with the fracture injury can be noted with regard to severity staging, so as to facilitate the decision making process regarding the urgency of therapy. For instance, the presence of segmental bone loss (B), or associated soft tissue loss (T) can be identified, and in very severe injuries any neurologic impairment associated with the specific injury (N) also can be designated. These are shown in the chart adjacent to the fracture (F) region by side of bone (R vs L). The presence and location of a traumatic amputation to an extremity can also be shown (black bar).

All of these data can in turn be related to the information contained in the other imaging diagrams, such as the presence or absence of peripheral pulses and the

extremity ABI requested in the Vascular images (Vasc). This permits the examiner to relate the surface injury characteristics to the fracture or ligamentous dislocation injuries of the underlying skeletal structures and any vascular or neurologic consequences.

7. Organ And Arterial Vascular System Injuries

Since the system is the invention finds particular applicability in Trauma cases, additional interactive anatomic diagrams were developed to permit the type and localization of organ and vascular injuries and their stratification by the severity grading system devised by Moore and colleagues (4-7). In these diagnostic image fields the "hot buttons" permit precise localization of blunt and penetrating organ injuries, with entry and exit wound symbols delineated as previously described. As each organ region, anatomic segment, or section of the biliary, pancreatic or vascular system is localized by the mouse cursor, it is outlined in red. When the choice is made and the mouse button activated, the name of the organ is shown in a box of the color of the causative agent (e.g., orange for gunshot, yellow for stab wound, pink for blunt contusion) and the location of entry and/or exit wound designated by **cause symbol**. Once the choice is made, then a **pop-up window** appears on screen and the user is asked to provide the Severity Grade [1-6] based on the Moore et al. (4-7) severity classifications. This choice determines the final color of the organ area injured and the numeric severity grade appears next to the box designating the organ or the chart. In this way the correct AIS 90 (8) and Abdominal Trauma Index (9) scores can be determined by the operating surgeon immediately after surgery, or when CT, or angiographic diagnosis has been made in non operative cases. This severity grading is also used to determine the correct ICD.9 code for each organ or structure injury.

a. Viscera (Thoracic and Abdominal Cavity Viscera)

In this image, as shown in FIG. 6 the thoracic and abdominal viscera are displayed for localization of injury by type of insult and severity grading. While the diagram is a hermaphrodite, the program limits the options with regard to the organs of generation by the designated sex in the original demographic field (i.e.,

in males the examiner cannot access the location for uterus, ovaries and vagina and vice versa). The specific severity grading qualifications for each particular organ are presented in a **pop-up window** as that organ or organ region (e.g., right lobe of liver) is chosen.

For illustrative purposes, this figure shows a trans diaphragmatic thoraco-abdominal gunshot wound, with entry into the lower lobe of the right lung, trans diaphragmatic entry into the right lobe of the Liver, with exit in the middle segment (middle lobe) of the left lobe of the Liver, entry into and exit from the body of the stomach, a through and through perforation of the transverse colon and a hematoma of the spleen. Each injury is graded according to the Moore et al (4-7) severity scheme.

8. Retroperitoneal Organs

The screen of FIG. 7 presents the retroperitoneal organs and their major vascular supply using the same conventions as above.

9. Liver

In similar fashion a more detailed description of hepato-biliary injury, major portal and hepatic venous injury and pancreatic ductal injury can be delineated as shown in FIG. 8.

10. Vascular

The screen diagram of FIG. 9 shows the anatomic scheme of the major arterial system, including the intra-cranial vessels, with each major segment or division designated. The exact site of injury and its cause can be localized by the mechanism "hot buttons" and the severity of injury designated by the Moore et al (4-7) system of grading using a **pop-up window**. In addition, the presence or absence of peripheral arterial pulses can be indicated as well as the ABI index for the extremities. Information from this diagram can be correlated with surface

injuries noted in the **Skin/Body** diagram for that patient (FIG. 1 screen) and with that patient's skeletal injuries (FIG. 4 screen).

11. Lung (Lung And Trachea-Bronchial Tree)

This screen diagram (which is not shown in the figures) demonstrates all of the anatomic segments of the right and left lungs, from frontal, posterior, lateral and medial (hilar) aspects, as well as the major divisions of the trachea bronchial tree. It allows not only for localization of penetrating injuries, but also for delineation of areas of lung contusion, pneumonitis, ARDS Abscess and empyema. It also permits the recording of localization of foreign bodies, or lacerations in the tracheobronchial tree as found by bronchoscopy.

As will be understood, additional anatomic screens may readily be designed and implemented to provide detailed recording of other injury conditions, such as peripheral nerve injuries, more detailed orthopedic injury descriptions, injuries to the pelvis and its critical vasculature relevant to pelvic fracture mechanisms, the detailed anatomy of the spine, the thoracic cardiovascular anatomy and that of the intrathoracic esophagus, the neck, and the brain and its coverings, as well as critical body cross sections compatible with the recovery of computer tomographically delineated organ injuries.

C. RESUSCITATIVE AND SURGICAL THERAPY

Using the information obtained in the Diagnostic Modules, the invention facilitates a designation of the utilization of standard acute resuscitative and emergency surgical procedures and their CPT codes. This Resuscitation Critical Care **pop-up window**, as shown in FIG. 10, is activated by placing the cursor in the **Sx** box in FIG. 1, after the mandatory examinations (Screens 1-4) are completed. For more complex operative trauma surgery, the original injury screens (FIGs. 2-9) will be returned with the designated injuries noted. Now, as each designated injury site is delineated with the mouse, a **pop-up window** shows the injury name and ICD.9 code. A second **pop-up window** below the injury designation screen presents a

list of trauma related surgical procedures for that organ or structure and their CPT codes -- fees for each code can also be added to assist the billing process. The procedure performed for that organ is then designated by touching its name with the mouse cursor, this then links the organ injury and severity grade and its ICD.9 code with the chosen surgical procedure and its CPT code.

A format for demographic patient information which can be entered by a record clerk in the Patient Admitting Area contains data concerning the patient's name, address, social security number, hospital record number, insurance information and billing address, as well as information concerning the patient's chief complaint, mode of entry into the hospital and condition at the time of entry. Also, other relevant admission information can be entered. These data can be transferred through the data base to the anatomic screens, so that the physician only needs to enter the clinical information. These data are also available to the operative note and billing information screen.

The procedure and operative note section of the program allows the linkage of the patient's diagnostic information to therapeutic information regarding specific procedures or operations performed on the patient. The screen displaying Patient Reporting is set forth in FIGS. 13A and 13B. The primary patient data from the demographic information is automatically entered in the operative note. The surgeon then has the option of designating which type of category of procedures he is dealing with (e.g., resuscitation, trauma consultation, critical care, closure of superficial lacerations and plastic reconstructive procedures, and various major operations by region of the body, including the nature and location of body incisions. When these data have been linked to the ICD.9 code, they can be verified by the operating surgeon directly on the screen display. Then there is a set of questions (Examples of whose answers have been shown in FIGS. 14A-14D) regarding the patient's intraoperative complications, features of therapy, such as blood transfusion, chest tubes, placement of tubes for drainage of a hollow viscus or placement of a feeding jejunostomy tube. The physiologic data relevant to the

patient's condition at the conclusion of surgery can also be provided. These data are organized into a formal document which can serve as an operative note or procedure record. The data from this concatanted record is available to be entered into a standard billing system through interface with a hospital billing data base.

D. DIAGNOSTIC AND THERAPEUTIC RECORD KEEPING

As will be understood from the foregoing discussion, the initial delineation of anatomic injury locations and the severity of organ and skeletal injuries are specifically designated by the examining trauma attending surgeon, surgical resident, or consultant. The system thereafter permits these data to be reviewed and diagnostic recording errors corrected by selected individuals who have authorized access to the data for such purpose. This allows for a precise nomenclature for the injury and its complication or severity grade to be organized in any one of several desired orders. This nomenclature also permits the assignment of a Diagnostic Code such as ICD.9 to be done in automated fashion, or to be added or adjusted later by an experienced record coder.

As an example of another related use of this feature, FIG. 11 shows a **pop-up window** listing the fractures sustained by a Motor Vehicle Crash (MVC) study patient for use in a screen diagram of the interior of the front seat passenger compartment of a motor vehicle. In this diagram each fracture can be selected by use of the mouse cursor and then assigned to a particular compartment structure by first touching the "hot button" for the specific injury and then the location on the automobile passenger compartment diagram. This particular screen display comports with parameters described in a National Highway Traffic Safety supported study of Motor Vehicle Crashes (10). This image also allows information about the driver or passenger status of the victim, the direction of the MVC crash, the victim's use of restraints and their type, and the consequences of the crash to the vehicle with regard to the passenger compartment integrity.

Other such special use screens can also be readily created, since all of the alpha-metric data is resident in a relational data base. The multi-patient data base can also be migrated to one of the standard statistical data bases (e.g., SAS, SPSS) for statistical analysis.

E. THERAPEUTIC ADVISORIES (Rx)

A series of therapeutic advisories has been developed in conjunction with the system of the invention to relate the medical and surgical recommendations for initial therapy to the specific types, location and severities of injuries delineated in the diagnostic examination diagrams. These data are based on the primary data entered and can be brought to the examiners attention by activating the **Rx** advice box present on each body image diagram. An example of a portion of one such therapeutic advisory is shown in FIGs 12 a, b & c. While these specific advisories are based on presently developed protocols, they can be changed as new information or new therapeutic regimens are developed, so as to maintain the advice as current as possible.

In FIG. 12, the recommended fluid therapy for the mock patient, Joseph Smith, age 44, weight 100 kilograms, height 6'2", sex male, shown in FIG. 1, are presented. As indicated in the initial figure, the illustrative burn trauma was secondary to flame with a electrical component. The percentage of first, second and third degree burns are shown in FIG. 1 and the percentage of the second and third degree burns have been cumulated as a basis for fluid therapy. This is shown in FIG. 12A, where the basic data are repeated, the body surface area is computed and the fluid requirements for the first and second 24 hours are shown based on a modified Brooke Army Burn Center protocol. (However, if desired, an alternate protocol, such as the Parkland formulation can be substituted). In this formula, crystalloid fluid replacement therapy only is used during the initial 24 hours of treatment and a combination of crystalloid and colloid fluid therapy is used in the second 24 hour period. The program computes the volumes and the rates of fluid administration as a baseline. Note that therapeutic advisories are

also shown which indicate that the baseline rate of fluid administration is to be adjusted to maintain vital signs and to keep the urine output between 50-100 milliliters per hour. Cautions regarding the use of dextrose: salt solution modifications in the replacement fluid therapy appropriate to the patient's needs are discussed.

A conditional requirement for physiologic monitoring of patients with large burns, the percent burn sustained by Mr. Smith (40.9 percent) is noted, and the use and body weight adjusted dosage of inotropic agents to maintain a high cardiac output in the hyperdynamic range are shown (FIG. 12B). The use of agents to combat excessive vasoconstriction is noted and specific cautions as to when to obtain serial chest x-rays to evaluate fluid overload by pulmonary infiltration are shown. The need for frequent monitoring of plasma electrolytes, glucose and blood urea nitrogen, as well as blood gases is noted and their frequency indicated.

Since the patient was noted to have an electrical component to his large third degree burn, a warning is given to monitor the urine for evidence of myoglobinuria and a therapeutic program for urine alkalization to prevent renal failure is indicated. Since the patient was shown to have a circumferential burn, of face and neck, the need to consider airway intubation and the possibility of early escharotomy with regard to both the neck and the chest are indicated in subsequent cautions. The need to evaluate the patient for evidence of respiratory burn and the preferred diagnostic technique (bronchoscopy) is indicated.

The presence of a circumferential chest and limb burns is noted and the need for monitoring of extremity pulses and fascial compartment pressures is indicated with a requirement for thoracic faschiotomies should ventilatory tidal volumes decrease, or extremity faschiotomies if limb muscle compartment pressures becomes elevated (FIG. 12C).

The use of general therapeutic modalities such as the use of a nasogastric tube and or gastric antiacid therapy as well as its dose are noted. The importance of tetanus toxoid and antibiotic prophylaxis against staphylococcus and streptococcus organisms is indicated. The approach to wound cleansing and local antibiotic suppressant therapy is suggested. The use of early excision of the areas of third degree burns is recommended. Finally, because of the electrical component, a monitoring of ECG and the exploration of all extremities involved in the electrical burn is indicated for the identification of necrotic muscle. The need for early amputation for extensive muscle damage due to an electrical burn is also noted.

In other therapeutic (**Rx**) advisories different protocols are indicated; for example, patients with spinal cord disfunction are delineated as mandatorily requiring a therapeutic dose of corticosteroids and the steroid dose and dosing program, computed on the basis of the patient's body weight, are given. Additionally, the need for acute nasogastric tube decompression in cervical spinal cord injury patients is indicated. The role of foley catheter decompression to prevent bladder distention, especially if complete spinal cord injury is present is stressed. In brain injury, the need to maintain a high cardiac output and a blood pressure sufficient to over come the reduced brain compliance is emphasized and the importance of the recognition of diabetes insipidus (DI) is noted and a program for DI urinary replacement IV therapy and the use of vasopressin therapy to control the excessive renal fluid losses is detailed.

While the specific cautions shown can be modified at any time to reflect changes in the recommended therapy or improved diagnostic capabilities, their illustrative inclusion here exemplifies how the physical examination and physiologic studies captured in the diagnostic examination portion part of the program can be used to direct and modulate the protocols for therapy of the acutely injured patient. This becomes especially important when such patients may have to be managed by individuals who are not skilled in acute trauma or intensive care management and where their diagnosis and therapy may have to be carried out at a location far

from a definitive hospital setting, or in circumstances where communications may be disrupted and transportation from the location of injury to a definitive care facility may be delayed or prevented for a critical period (military setting, Space Station accident, or natural disaster).

It will be understood that the embodiments described herein are merely exemplary of the principles of the invention, and that a person skilled in the art may make many variations and modifications without departing from the spirit and the scope of the invention. All such variations and modifications are intended to be included with the scope of the invention as defined in the appended claims.

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WHAT IS CLAIMED IS:

1. An automated system for management of data related to disease and injury conditions comprising:

display means operative to cause information to be displayed for a user via a graphical user interface;

diagnostic examination means cooperatively linked with said display means for guiding and enabling a graphical delineation of said conditions via at least one of a plurality of anatomical images, and for recording said conditions and associating said recorded conditions with other relevant data respecting the subject of said disease or injury condition;

interface means for enabling interaction between said user and said diagnostic examination means; and

processing means cooperatively linking said interface means and said diagnostic examination means whereby said delineated condition data is recorded and categorized, and additional diagnostic information, as appropriate, is caused to be displayed to said user.

2. The automated data management system of Claim 1 further including advisory means operating in conjunction with said processing means whereby therapeutic information relevant to said condition data is caused to be displayed at the option of said user.

3. An interactive data management system for delineation and recording trauma and surgical conditions, comprising:

graphical user interface means for establishing an interface, via a display means, between a user of said system (hereafter "examiner") and a capability of said system for processing, storage and retrieval of data related to said conditions;

diagnostic examination means including means for establishing at said graphical interface a plurality of anatomic images whereby said examiner is

enabled to graphically indicate details of said conditions and further including means for entering coding and classification data related to said condition via said graphical interface;

input means supporting interaction via said graphical user interface between said examiner and said system;

processing means for operating on information supplied to said system via said graphical user interface, including a processing function wherein said graphical information is converted to a corresponding textual form and further wherein said graphical information and said corresponding textual information is caused to be stored in a database, and further including a linkage function wherein a linkage is created between said supplied graphical information and other functions of said system, including other data available to said system;

advisory means operatively linked to said supplied information for providing to said examiner therapeutic information related to said condition; and

analysis means for operating on said condition related data to provide an output in a preselected form.

4. The interactive data management system according to Claim 3 wherein said diagnostic examination means operates to support delineation by said examiner of physiologic parameters of a traumatic injury on a displayed image of relevant anatomical structure.

5. The interactive data management system according to Claim 4 wherein traumatic injuries may be delineated with regard to their cause, severity and location on a body surface and within one or more organs.

6. The interactive data management system according to Claim 3 wherein said delineated and recorded condition information includes physiologic and demographic data for a patient being examined.

7. The interactive data management system according to Claim 3 further including a data interface with physiological monitoring systems and with radiological image data bases.

8. The interactive data management system according to Claim 3 further including a graphical presentation of patterns of multivariable physiological data describing, classifying and quantifying an adequacy of a patient's host defense response to injury.

9. The interactive data management system according to Claim 3 wherein said analysis means supports output reports directed to medical record keeping.

10. The interactive data management system according to Claim 3 wherein said analysis means supports output reports directed to quality assurance functions.

11. The interactive data management system according to Claim 3 wherein said analysis means supports output reports directed to third party carrier reimbursement systems.

12. The interactive data management system according to Claim 3 wherein said condition data is stored in a time sequential record for a given patient, thereby providing immediate reference to changes in said patient's condition.

13. The interactive data management system according to Claim 12 wherein said time sequential patient records are provided in both graphical and textual formats.

14. The interactive data management system according to Claim 3 wherein said advisory means provides state-of-the-art protocols and caveats relative to specific conditions manifested by a patient.

15. The interactive data management system according to Claim 3 wherein said advisory means provides drug dosage and protocols of administration for generally accepted urgent therapeutic agents.

16. A method of interactive data management supporting a delineation and recording of trauma and surgical conditions, comprising:

establishing a graphical user interface, via a display means, between a user and a means for processing, storage and retrieval of data related to said conditions;

displaying at said graphical interface a plurality of anatomic images whereby said user is enabled to graphically indicate details of said conditions and further for entering coding and classification data related to said condition via said graphical interface;

processing information supplied by said user via said graphical user interface, including a conversion of said graphical information to a corresponding textual form and further causing said graphical information and said corresponding textual information to be stored in a database, and further including an establishment of a linkage between said supplied graphical information and other functions of said means for processing, storage and retrieval including other data available via said means for processing, storage and retrieval;

linking to said supplied information to a database of therapeutic information for providing to said user therapeutic information related to said condition; and

operating on said condition related data to provide an output in a preselected form.

17. A patient management system architecture using a graphical user interface based on real time transaction processing objects to provide interaction between a medical professional and a stored data base, comprising

means for producing a vector map of an anatomical image and for causing said image to be displayed;

means for selecting, via said graphical user interface, a coding indicative of a patient's condition;

means for accessing a data base for storage and retrieval of data related to said patient's condition;

means for entering data based on selection at said graphical user interface from among a plurality of predefined patient conditions;

means for automatically providing to a user medical information related to said patient's condition;

wherein a user is enabled, via said graphical user interface, to graphically specify an injury condition, to select a condition code, and to receive medical advisories related specifically to said injury condition specified by said user, and wherein further all data entered by said user is stored in a time sequential record.

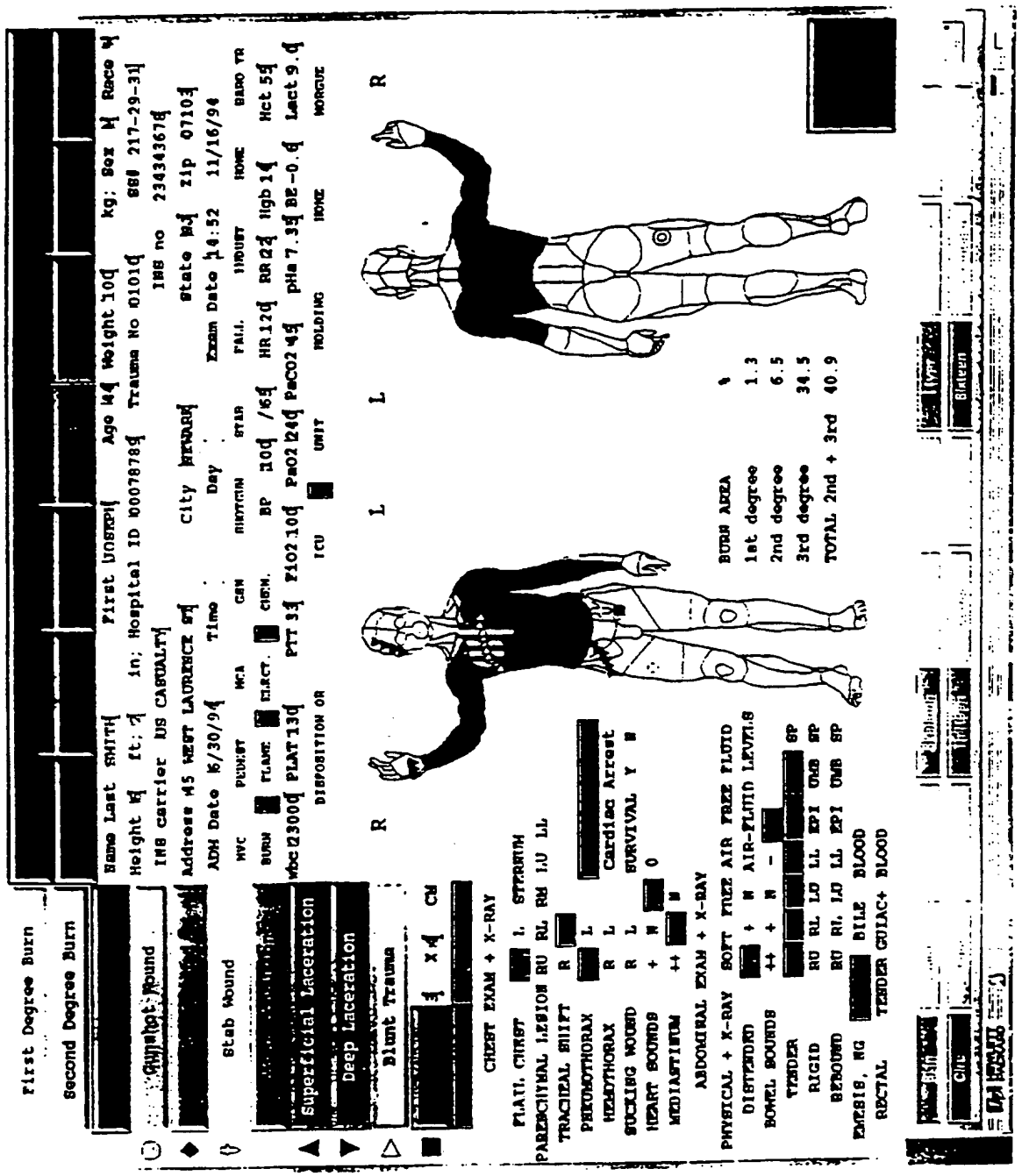



FIGURE 1

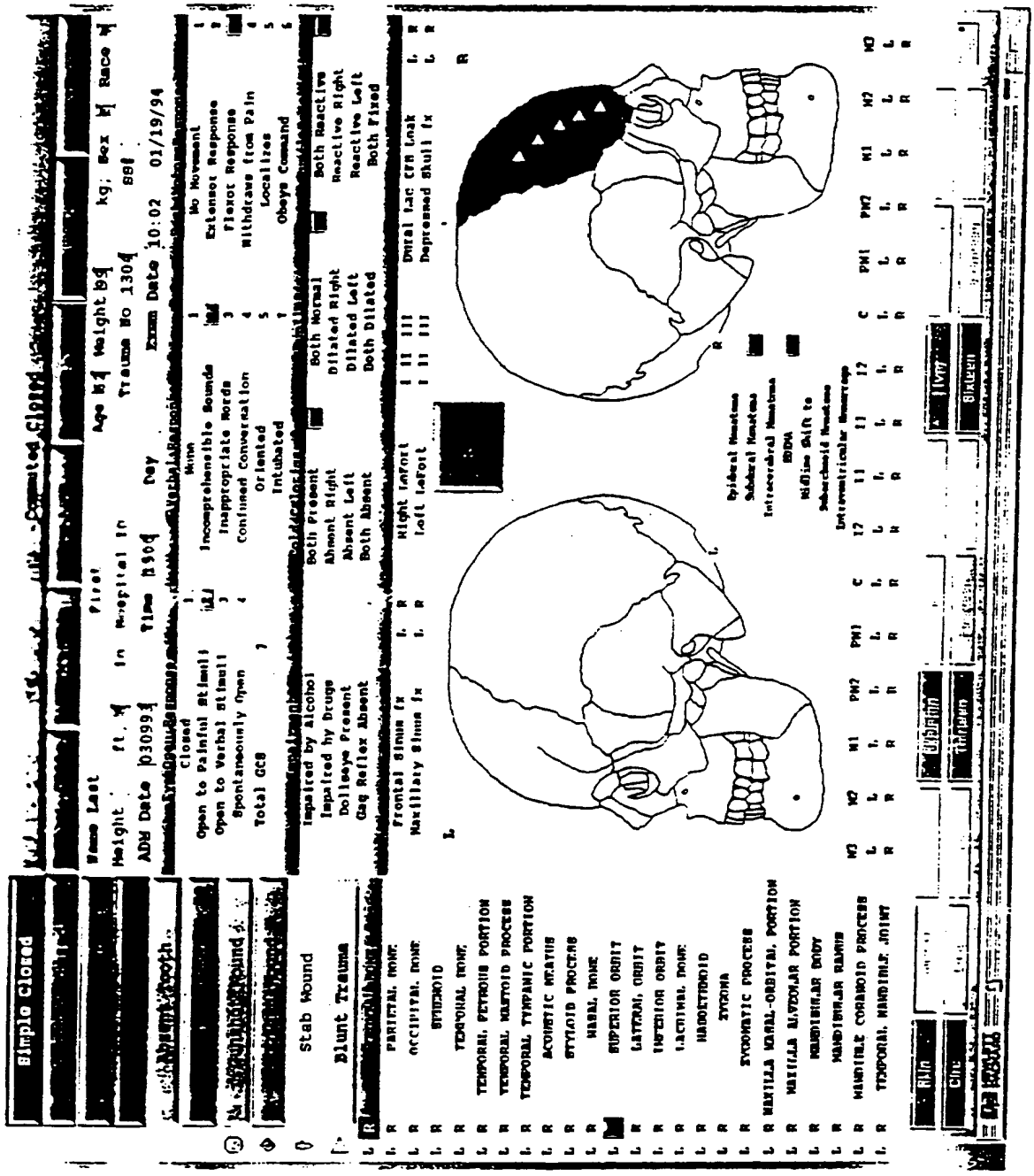



FIGURE 2

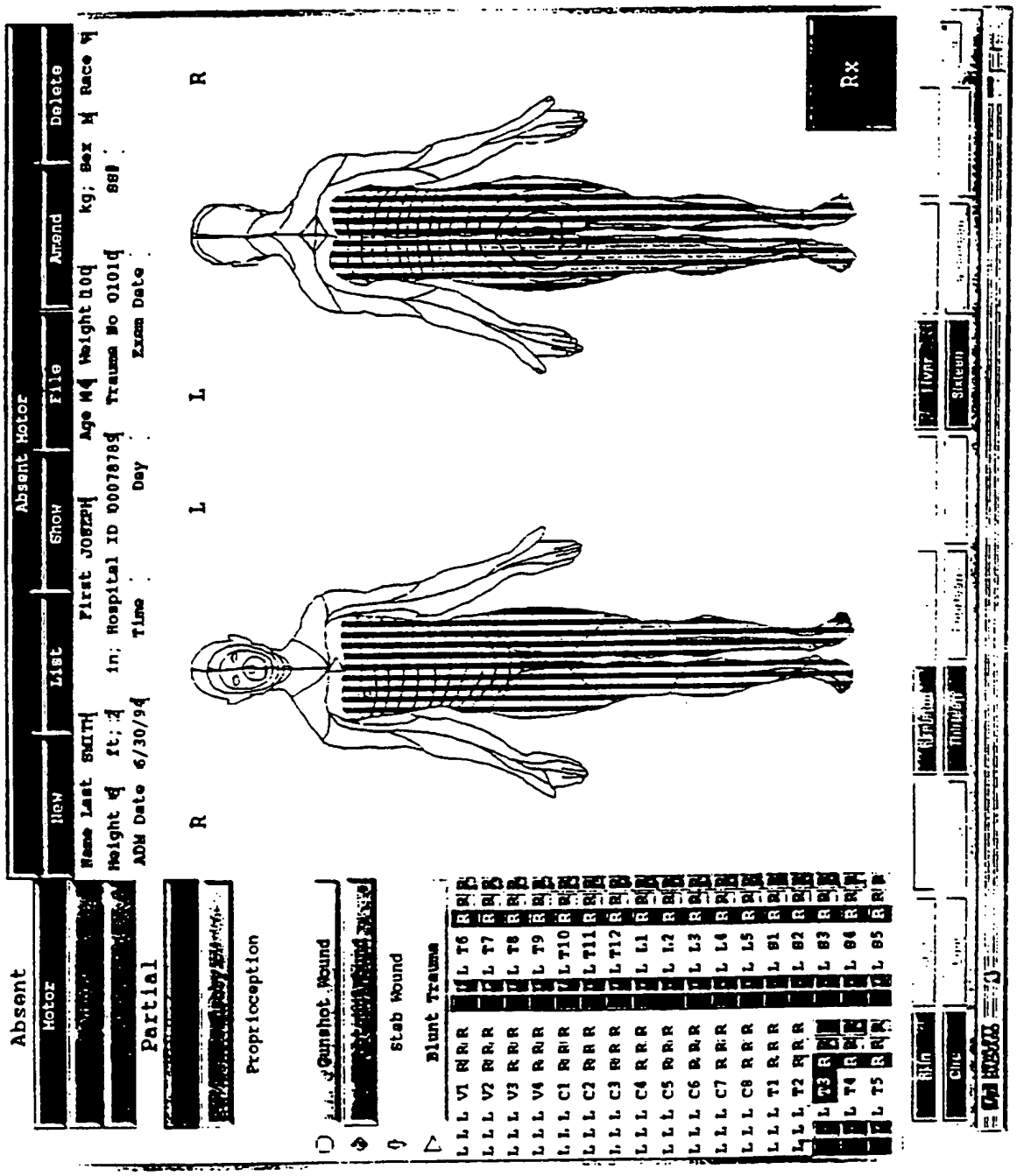

Absent
Motor
Absent Motor
New
List
Show
File
Amend
Delete
Partial
Proprioception
Gunshot Wound
Stab Wound
Blunt Trauma
R
L
L
R
Rx

FIGURE 3

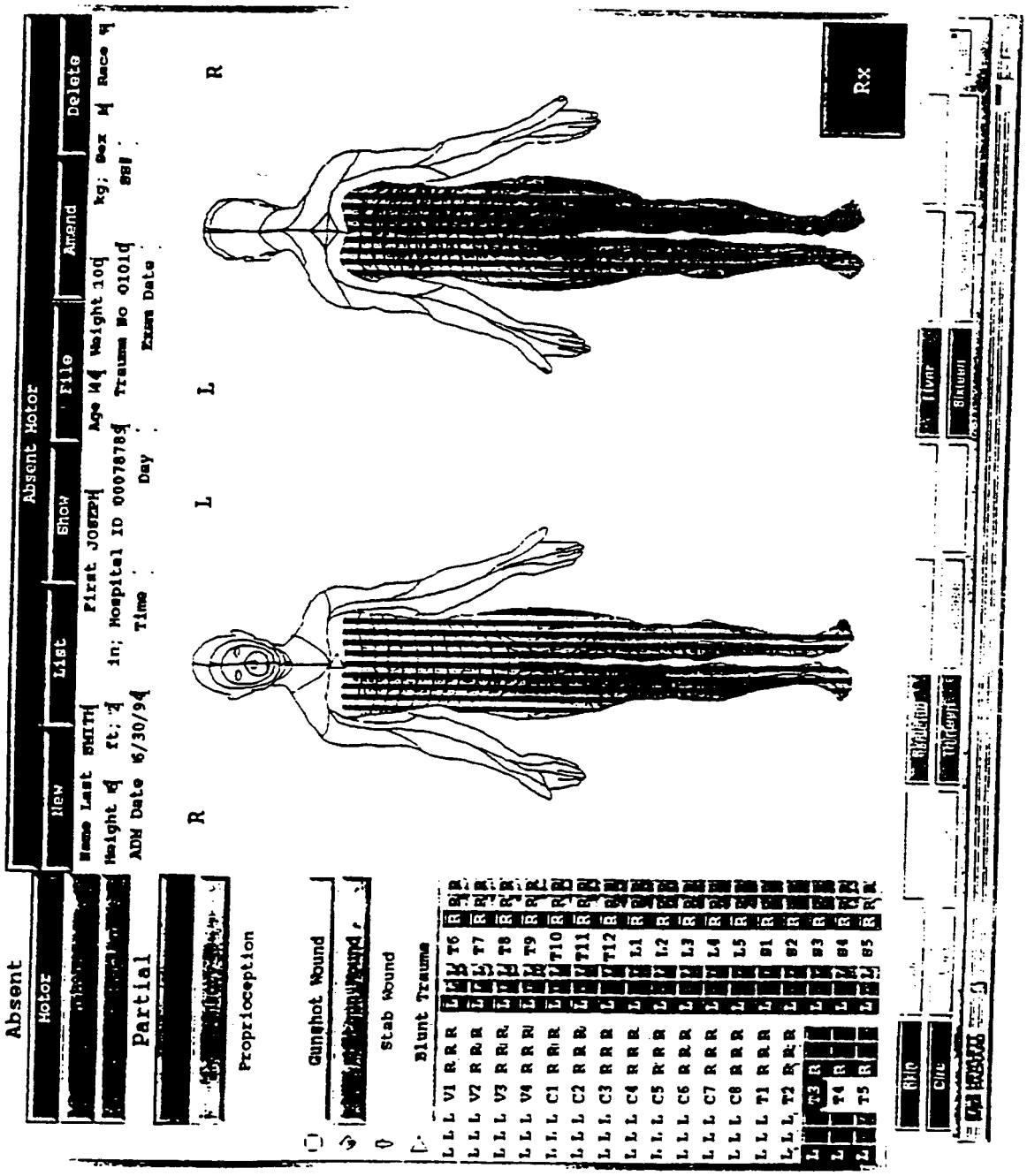

Absent Motor
New
List
Show
File
Amend
Delete
Rx
Absent
Motor
Partial
Proprioception
Gunshot Wound
Stab Wound
Blunt Trauma
R
L
L
R

FIGURE 4

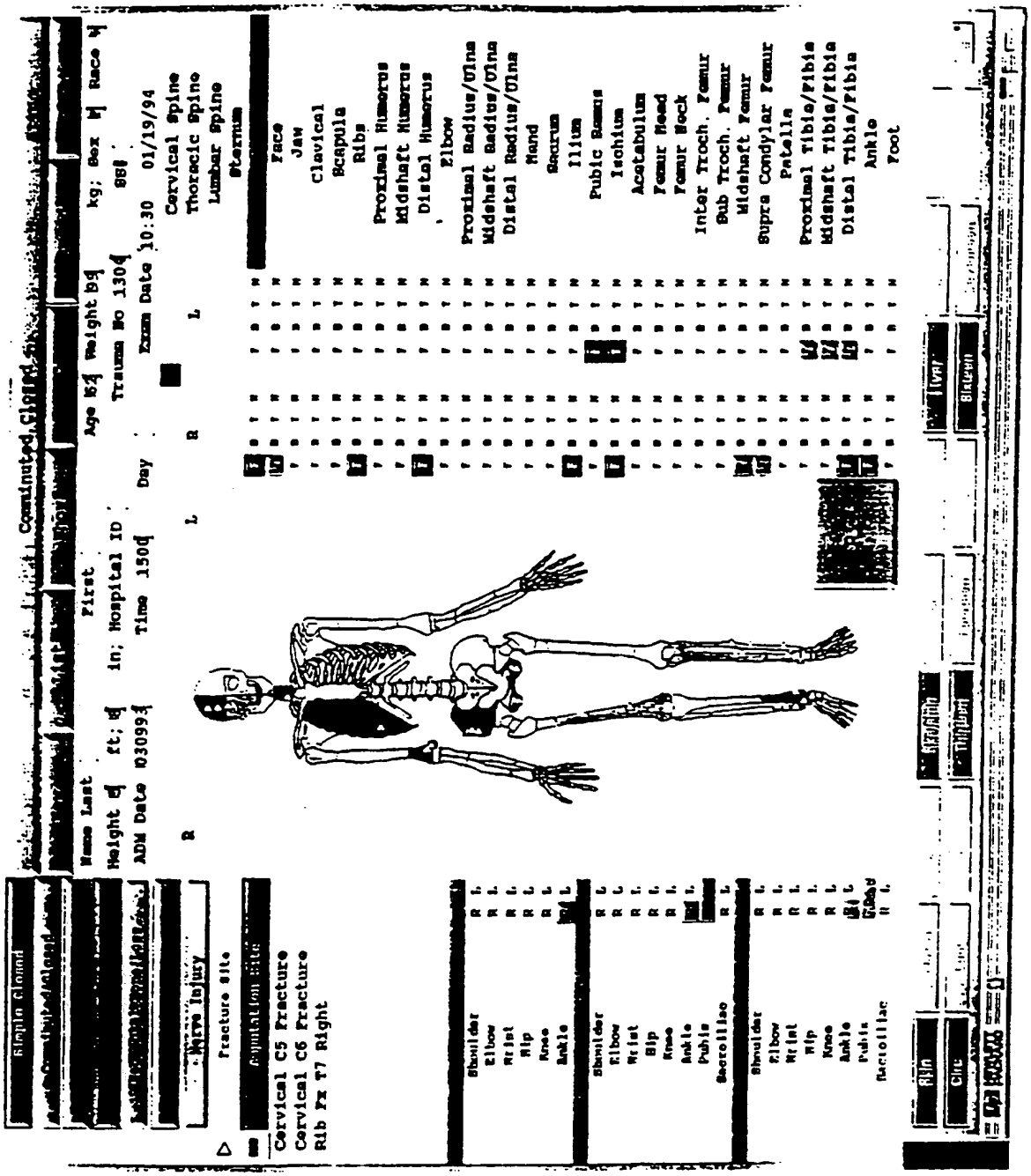



FIGURE 5

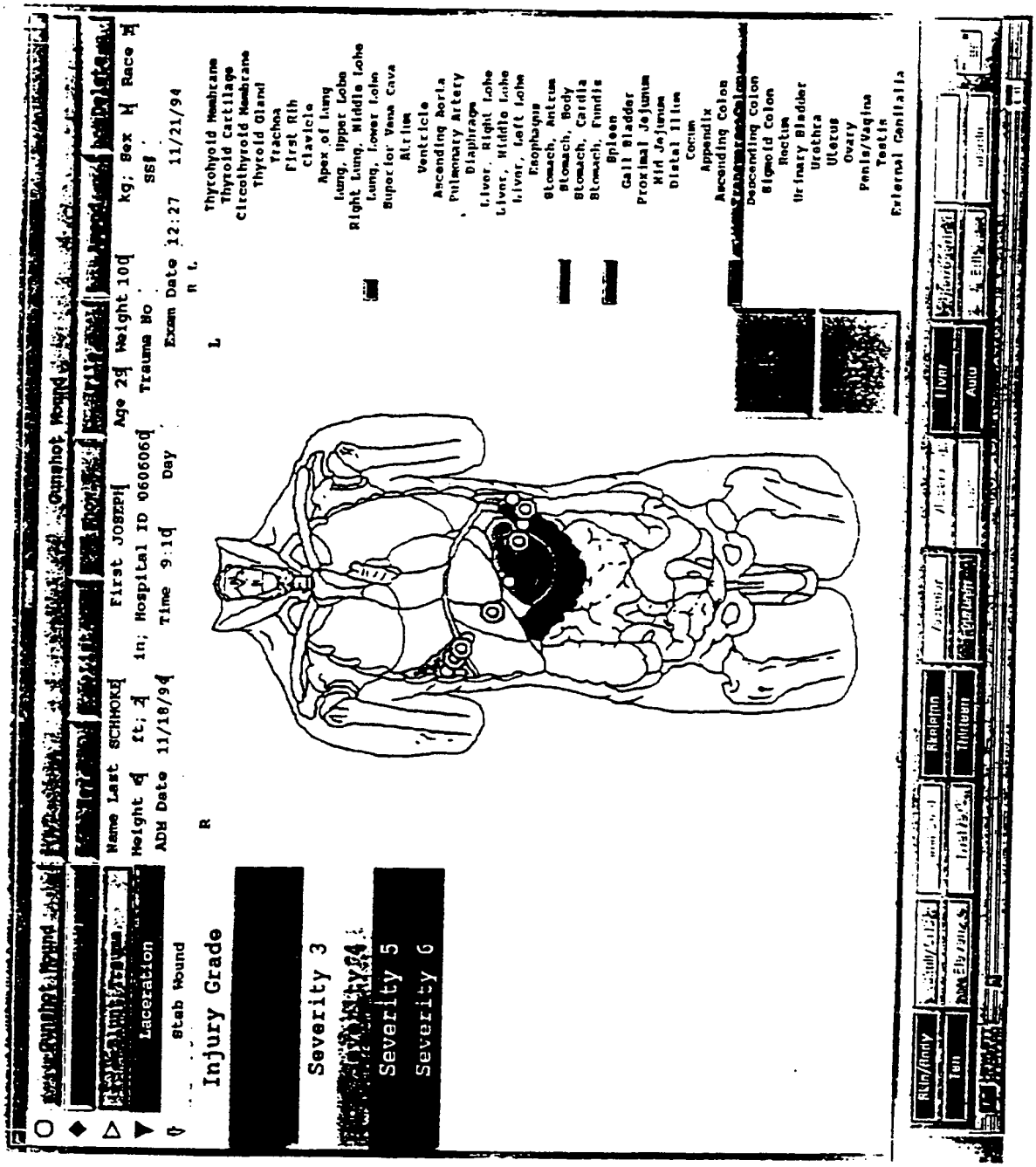



FIGURE 6

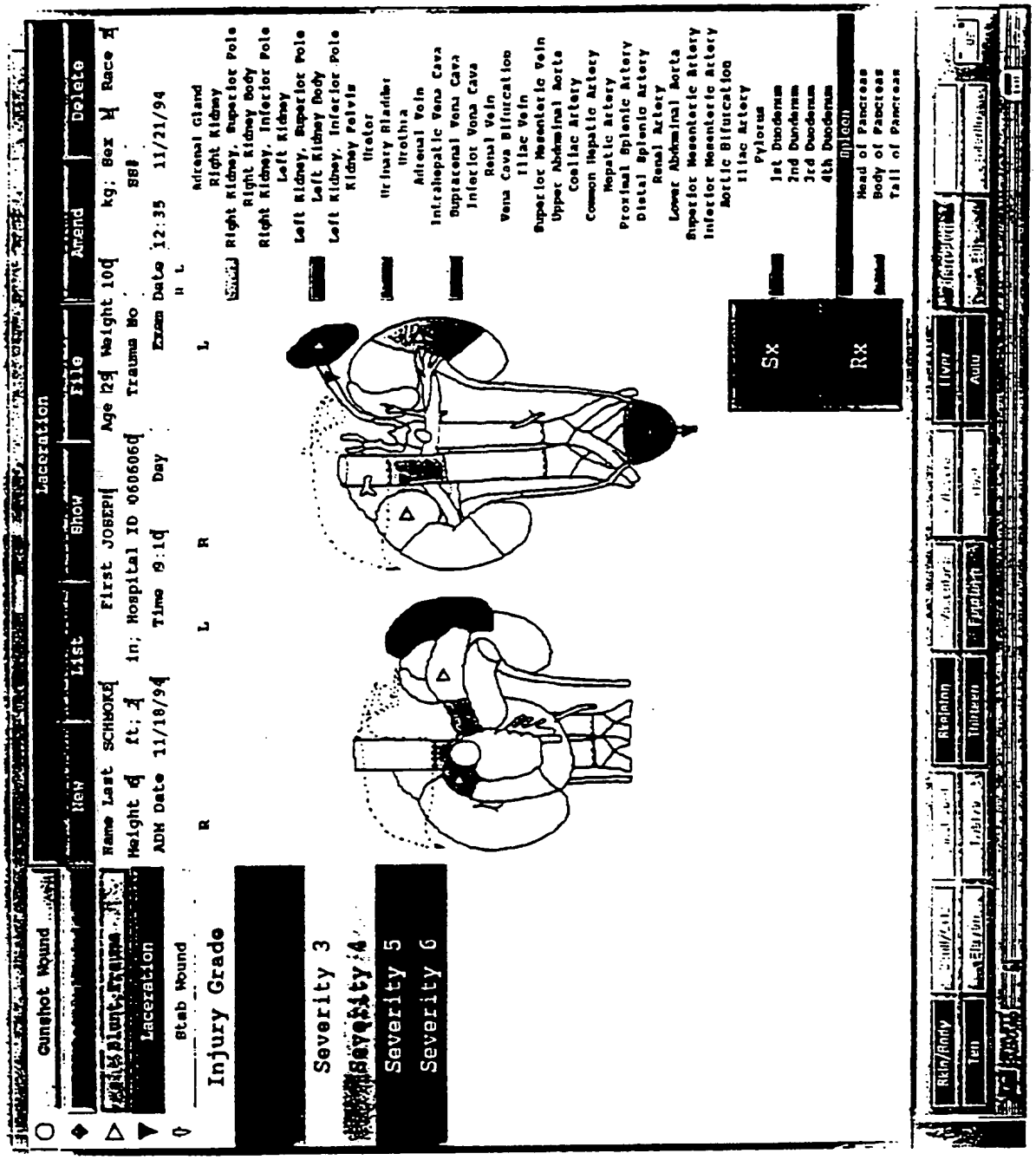



FIGURE 7

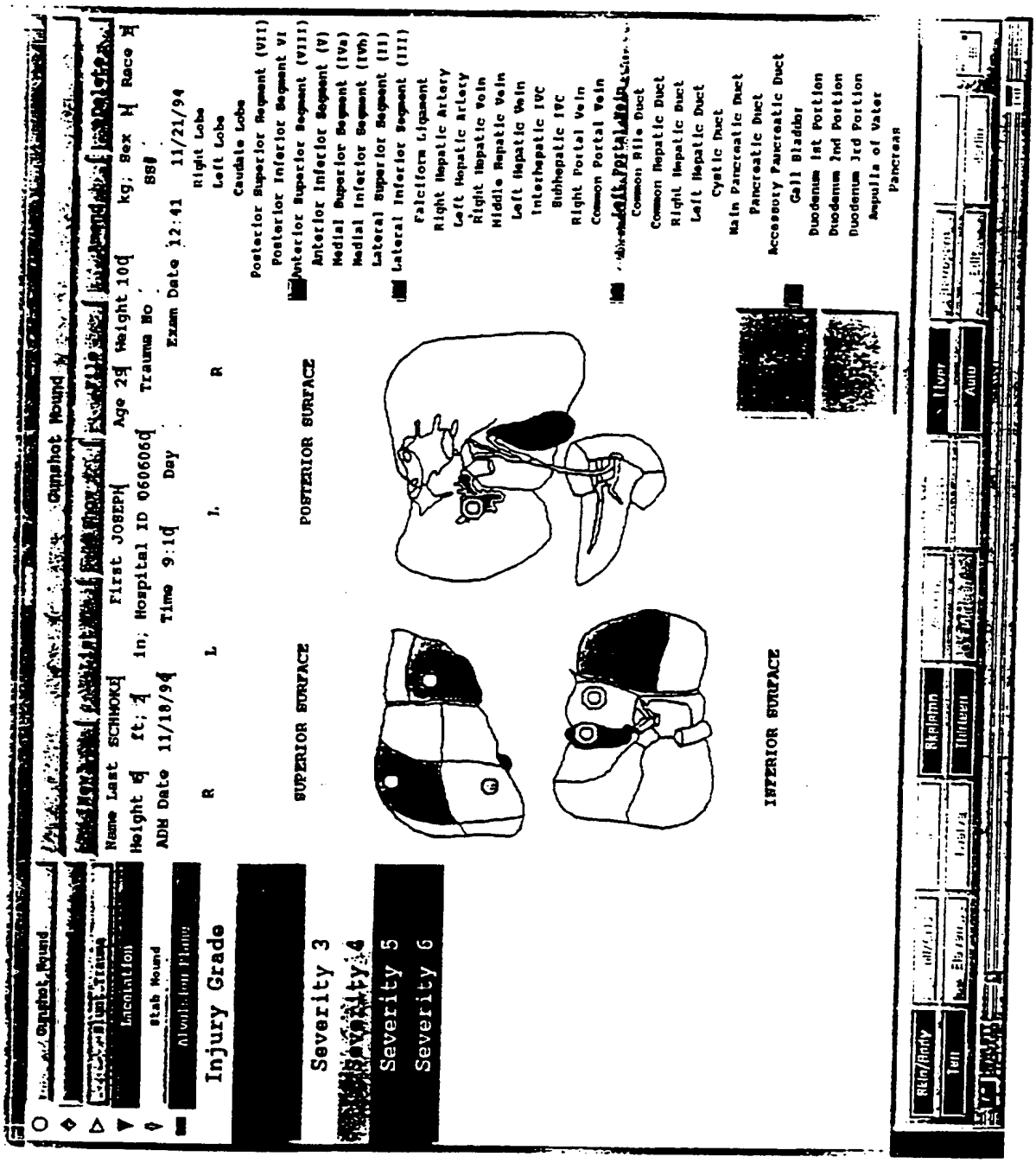



FIGURE 8

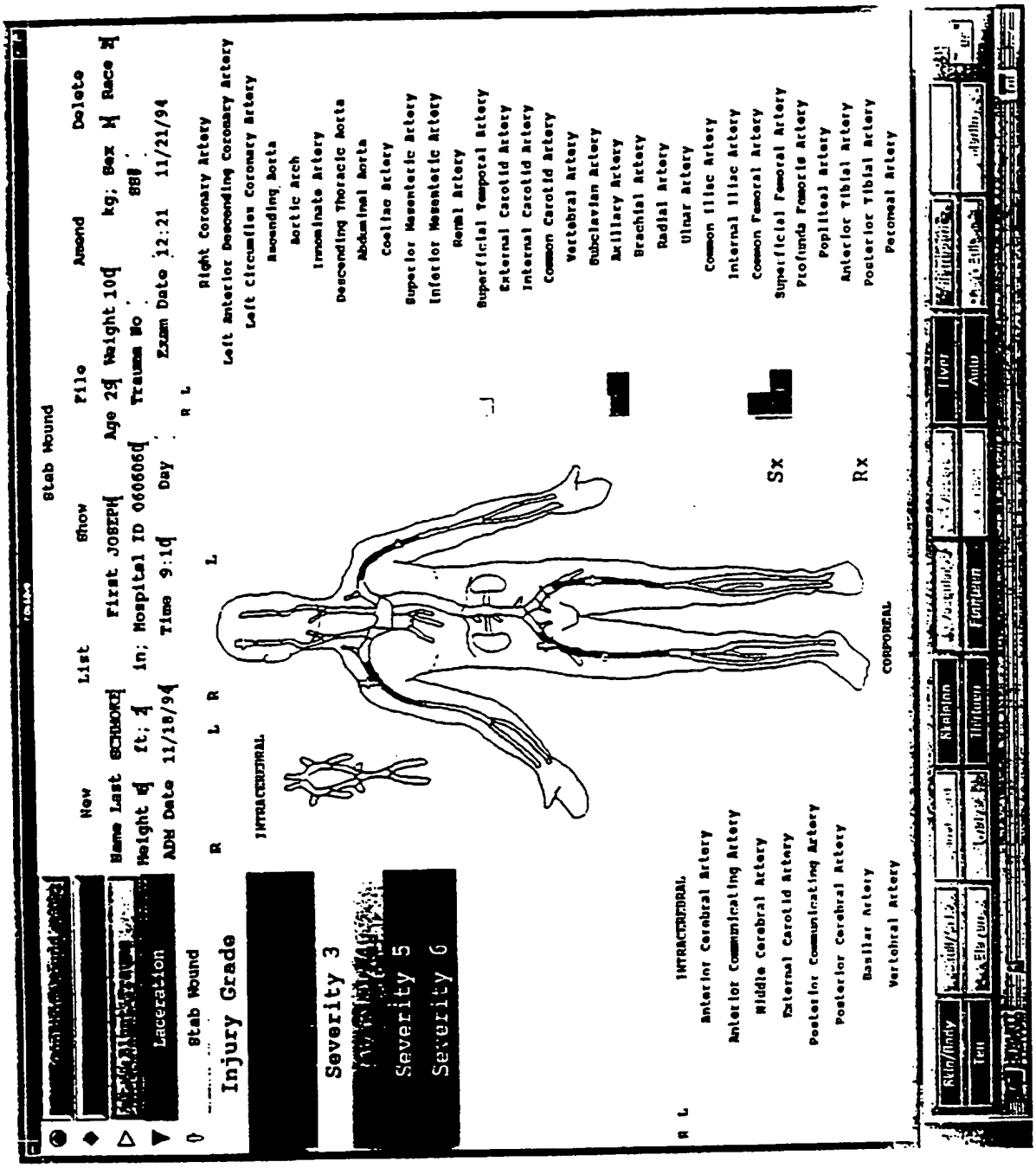



FIGURE 9

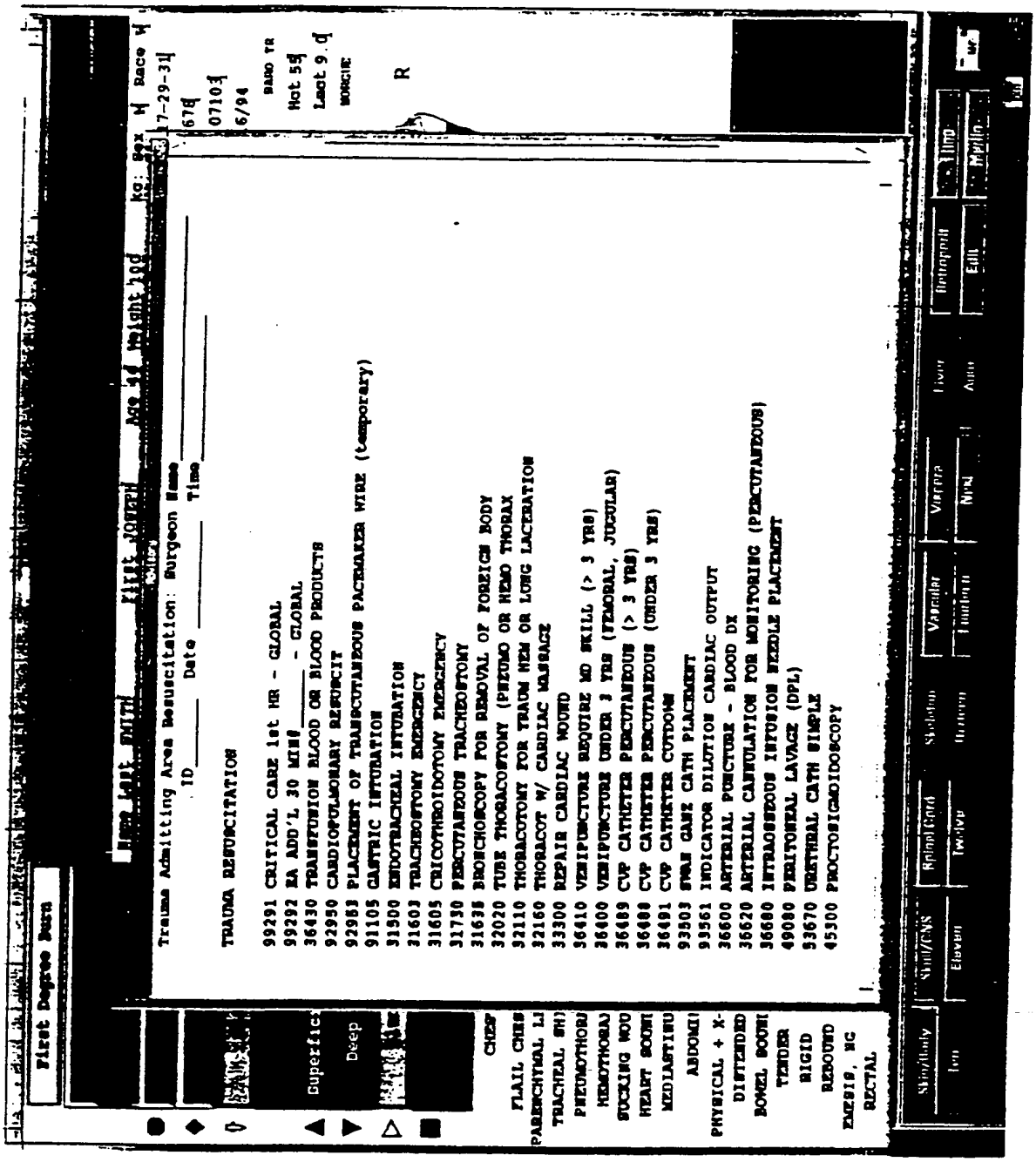



FIGURE 10

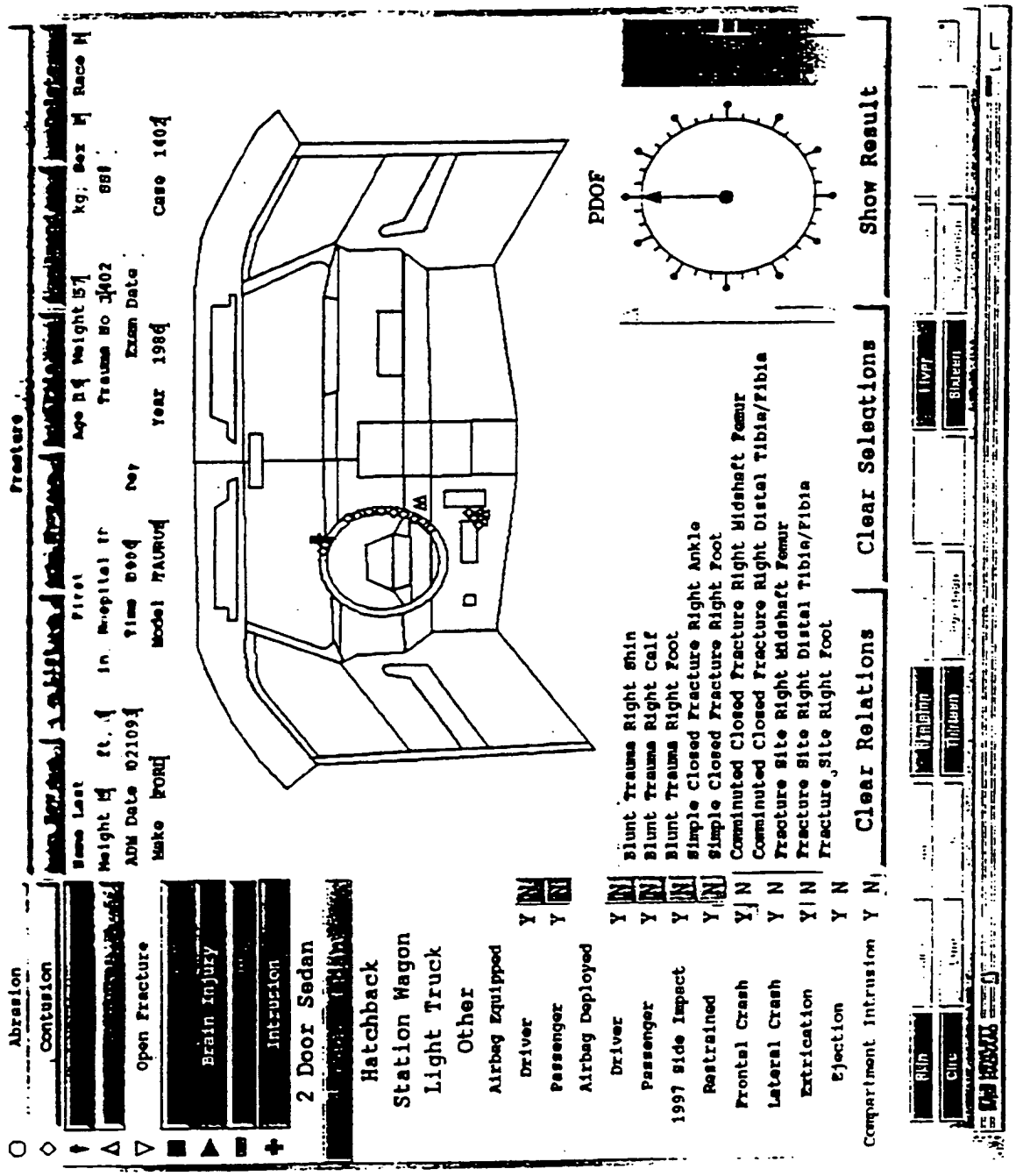



FIGURE 11

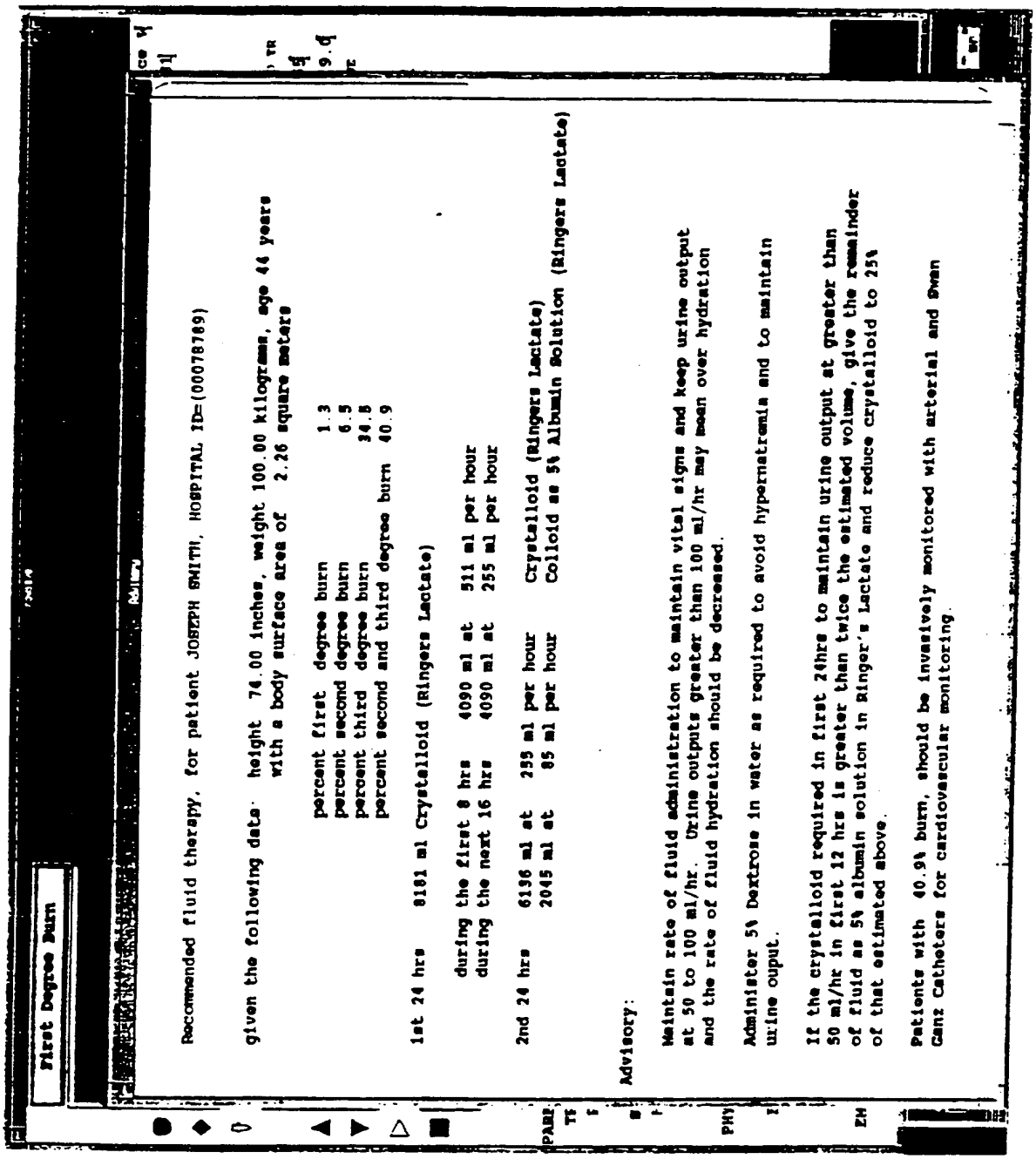



FIGURE 12A

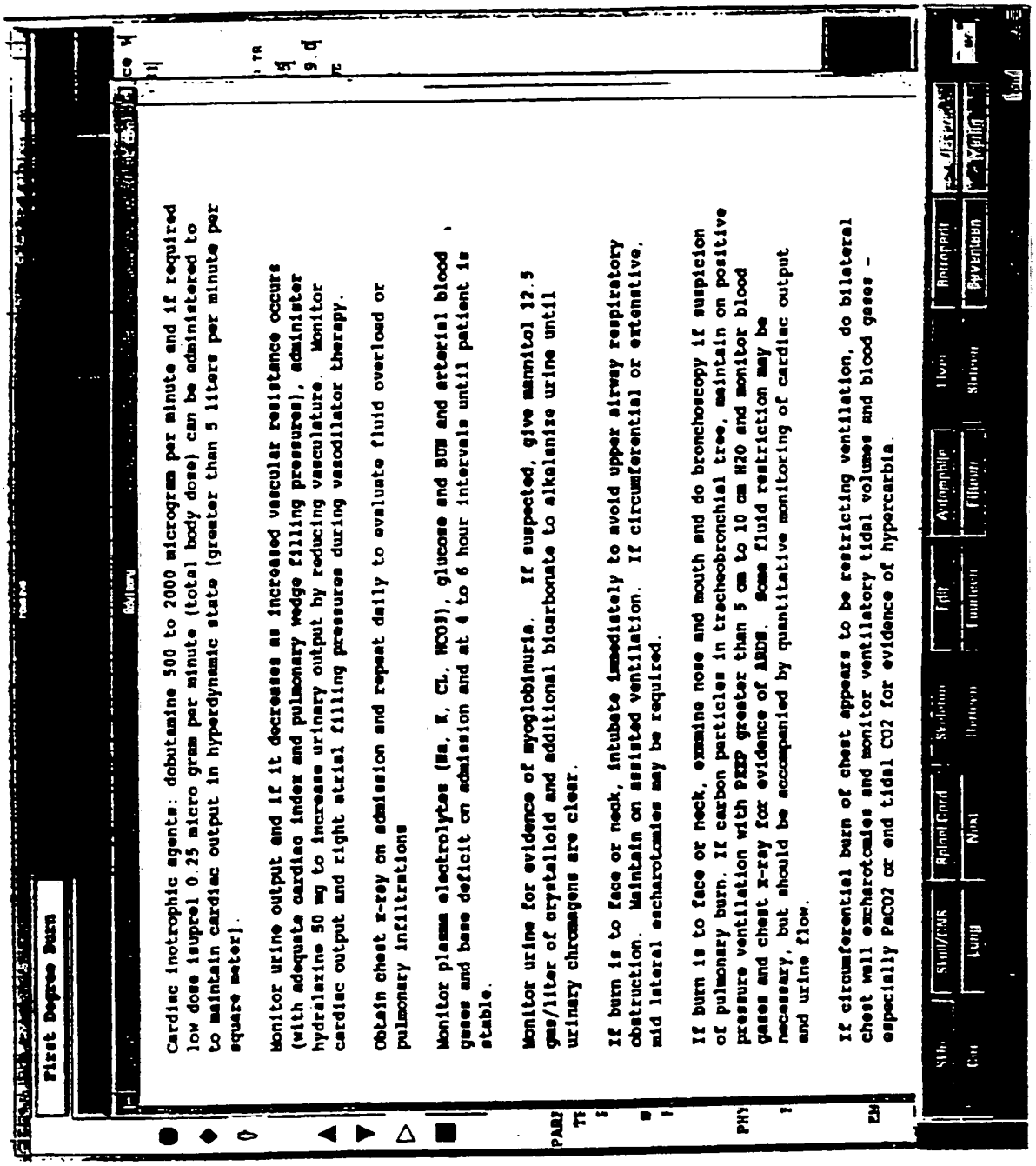



FIGURE 12B

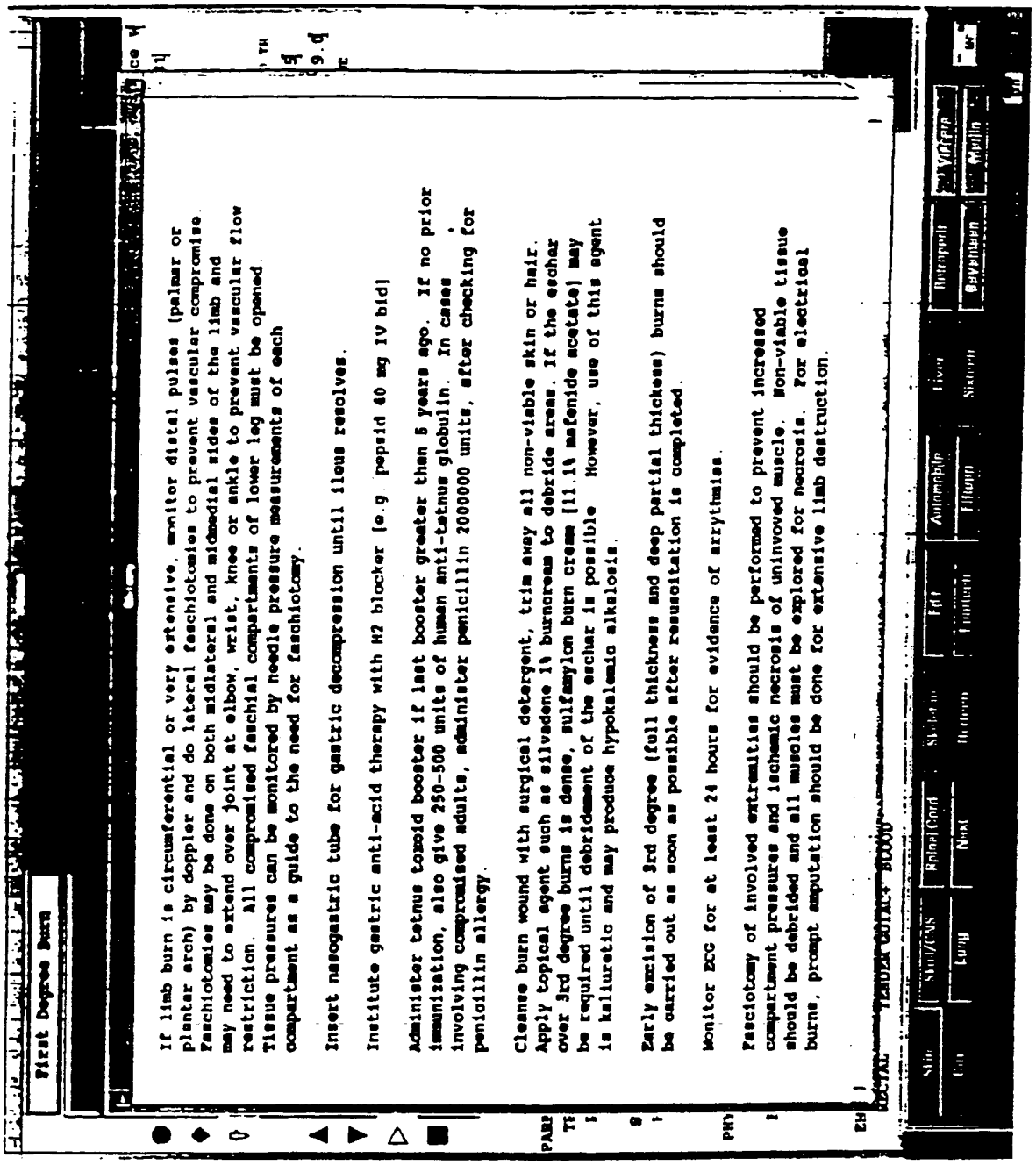
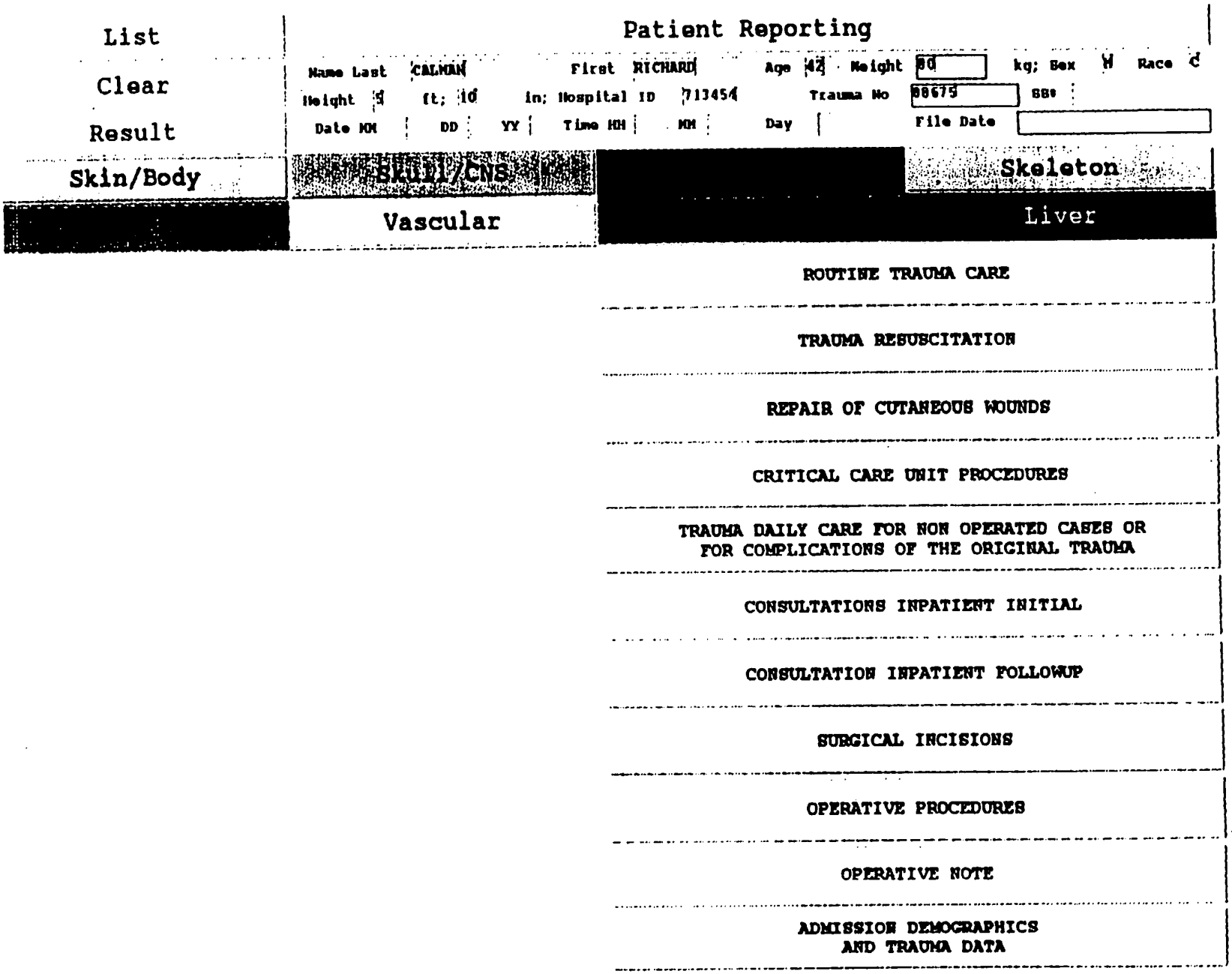
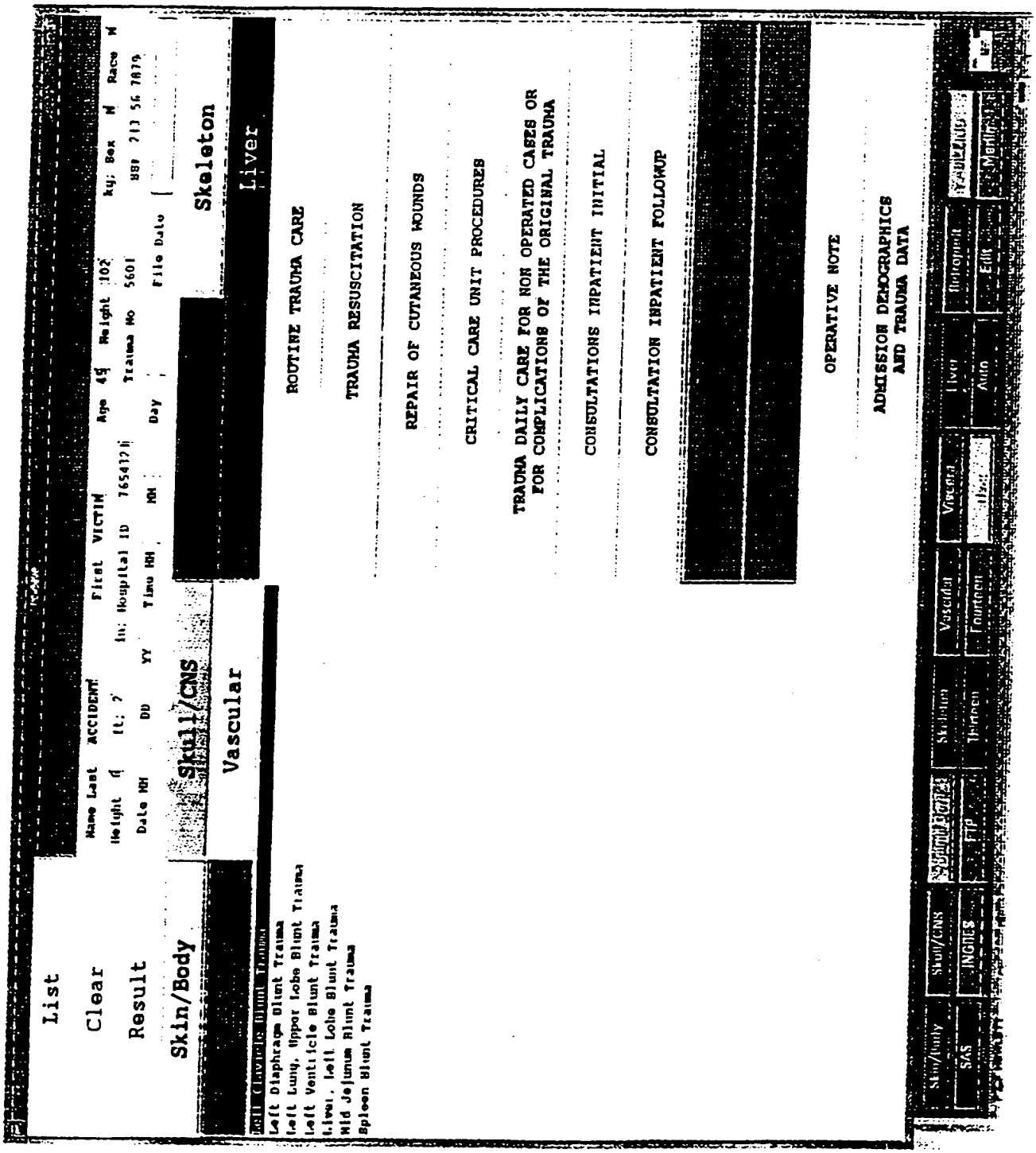



FIGURE 12C





# OPERATIVE NOTE: PHYSIOLOGIC VALUES AT END OF CASE

## PATIENT INFORMATION

PATIENT NAME ACCIDENT. VICTIM

STREET ADDRESS 1422 LAST CHANCE BOULEVARD

CITY DECAYED STATE NJ ZIP 010234

AGE 45 WEIGHT(kg) 102 SEX M RACE W HEIGHT FT 6 IN 2

HOSPITAL ID 7654321 MEDICAL RECORDS UNIT # 07654321

SS# 213-56-7879 FINANCIAL CLASS C

## HEALTH INSURANCE INFORMATION

INSURANCE PLAN BLUE + INSURANCE COMPANY NAME DELAYED
PAYMENT INSURANCE CORPORATION

EFFECTIVE DATE MM 01 DD 01 YY 1994

GROUP NO MR 027277 POLICY NO 1000123 TYPE - COVERAGE CODES COMP

## ADMISSION AND OPERATIVE DATES INFORMATION

ADMISSION DATE MM 11 DD 23 YY 95 TIME HH 10 MM 45

OPERATIVE DATE MM 11 DD 23 YY 95 DAYS PAST ADMISSION 0

## TYPE OF INJURY

MVC YES PEDEST NO MCA NO GSN NO SHOTGUN NO STAB NO FALL NO

INDUST NO HOME NO BARO TR NO BURN NO FLAME NO ELECT NO CHEM NO

Figure 14A

**PHYSICIANS**

SURGEON SIEGEL, JH ASSISTANT1 SMITH DC ASSISTANT2 JONES JR ASSISTANT3 FAITH JJ

**ANESTHESIA**

GENERAL ENDOTRACHEAL YES LOCAL NO REGIONAL NO SPINAL NO EPIDURAL NO

**DIAGNOSIS AND PROCEDURES**

Liver, Left Lobe Blunt Trauma
864.04 4 IV. Laceration: Parenchymal disruption 25-50% of hepatic lobe
VERTICAL MIDLINE INCISION

Left Lung, Upper Lobe Blunt Trauma
860.0 3 II. Laceration: Simple pneumothorax
32020 TUBE THORACOSTOMY

Left Ventricle Blunt Trauma
861.01 3 I. Blunt cardiac injury with minor ECG abnormality
33025 CREATION OF PERICARDIAL WINDOW (SUBXYPHOID APPROACH)

Left Diaphragm Blunt Trauma
862.1 3 II. Laceration: <2 cm
39501 REPAIR LACERATION OF DIAPHRAGM

Liver, Left Lobe Blunt Trauma
864.04 4 IV. Laceration: Parenchymal disruption 25-50% of hepatic lobe
47350 HEPATORRAPHY, SUTURE OF LIVER INJURY: SIMPLE

Spleen Blunt Trauma
865.03 4 IV. Hematoma: Ruptured intraparenchymal hematoma with active bleeding
38100 SPLENECTOMY, TOTAL

Mid Jejunum Blunt Trauma
863.20 4 V. Vascular: Devascularized bowel segment
44602 ENTERORRHAPHY SUTURE OF SMALL INTESTINE SINGLE PERFORATION

Figure 14B

| VITAL SIGNS AT END OF OPERATIVE PROCEDURE | | | | |
|---|---|---|---|---|
| BP 110 / 75 | HR 120 | RR 22 | %FIO2 50 | PaO2 108 |
| PaCO2 38 | pH 7.42 | BASE EXCESS +- 0.1 | | LACTATE 2.1 |

| | |
|---|---|
| INTRA OPERATIVE SHOCK | NO |
| INTRA OPERATIVE CARDIAC ARREST | NO |
| BLOOD GIVEN | YES |
| UNITS OF BLOOD GIVEN | 5 |
| INOTROPIC AGENTS USED DURING OPERATION | YES |
| THORACOTOMY | NOT SPECIFIED |
| MIDLINE STERNOTOMY | NO |
| THORACIC INCISION CLOSED PRIMARILY | NOT SPECIFIED |
| ABDOMEN CLOSED PRIMARILY | YES |
| PATIENT LEFT W/TEMP ABDOMEN CLOSURE | NOT SPECIFIED |
| PATIENT SURVIVED SURGERY | YES |
| INTUBATED ON TRANSFER | YES |
| IS PLANNED REOP REQUIRED | NO |
| ARTERIAL LINE | YES |
| CVP CATHETER | YES |
| SWAN-GANZ CATHETER | YES |
| NASOGASTRIC TUBE | YES |
| FOLEY CATHETER (BLADDER) | YES |
| CHEST TUBES | YES |
| CHEST TUBES LOCATION | LEFT |
| DRAINS | NO |
| JACKSON PRATT | YES |
| SUMPS | NO |

Figure 14C

| | |
|---|---|
| GASTROSTOMY | NO |
| FEEDING JEJUNOSTOMY | YES |
| COLOSTOMY | NO |
| COLOSTOMY MATURED | NOT SPECIFIED |
| ILEOSTOMY | NO |
| SUPRAPUBIC CYSTOSTOMY | NO |

**COMMENTS**

THIS PATIENT SUSTAINED INJURIES TO THE LIVER. SPLEEN AND DIAPHRAM. IN ADDITION THERE WAS A JEJUNAL LACERATION. THERE WAS A PNEUMOTHORAX FOR WHICH A CHEST TUBE WAS PLACED PRIOR TO SURGERY. AT OPERATION THE LIVER INJURY COULD BE DEALT WITH BY A SIMPLE LIVER SUTURE. THE SPLEEN REQUIRE SPLENECTOMY AND A SUTURE REPAIR WAS DONE TO THE JEJUNAL LACERATION. A JACKSON PRATT WAS PLACED IN MORRISON'S POUCH. THE PATIENT WAS IN GOOD CONDITION AT THE CLOSE OF THE PROCEDURE.
JOHN H. SIEGEL.MD

Figure 14D

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/16611

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G06F19/00 //G06F159:00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | SIXTEENTH ANNUAL SYMPOSIUM ON COMPUTER APPLICATIONS IN MEDICAL CARE, BALTIMORE, MD, USA, 8-11 NOV. 1992, ISBN 0-07-055023-9, 1993, NEW YORK, NY, USA, MCGRAW-HILL, USA, pages 787-788, XP002002189 BENOIT R G ET AL: "Direct physician entry of injury information and automated coding via a graphical user interface" see the whole document | 1 |
| Y | --- | 2-6,12, 15-17 |
| Y | WO,A,94 00817 (HEALTH RISK MANAGEMENT INC) 6 January 1994 see page 3, line 29 - page 4, line 25 see page 6, line 27 - page 20, line 12 | 2-6,12, 15-17 |
| | --- -/-- | |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 6 May 1996 | 22.05.96 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016 | Fournier, C |

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/16611

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US,A,5 325 293 (DORNE HOWARD L) 28 June 1994<br>see column 4, line 24 - column 5, line 66; claim 1; figure 5B | 1,3,10, 11 |
| A | DE,A,41 22 143 (DRAEGERWERK AG) 7 January 1993<br>see the whole document | 1,3,16 |

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 95/16611

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|---|---|---|---|---|
| WO-A-9400817 | 06-01-94 | AU-B- | 4652293 | 24-01-94 |
| | | CA-A- | 2121245 | 06-01-94 |
| | | EP-A- | 0600081 | 08-06-94 |
| US-A-5325293 | 28-06-94 | NONE | | |
| DE-A-4122143 | 07-01-93 | NONE | | |